
From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/7/2020 2:13:19 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Thank you, all!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Date: February 7, 2020 at 1:44:56 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Here you go. This is the four pager

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs

U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:44 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Megan can you please recirculate final so someone can print here?

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 7, 2020 at 1:42:57 PM EST
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Thanks

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 7, 2020 at 1:41:34 PM EST
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

OK if you all resend clean will print out and walk down

Laura M. Caliguiri

Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546



From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Sent: Friday, February 7, 2020 1:41 PM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Anna and (b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Friday, February 7, 2020 1:38 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

(b)(5)

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: McSeveney, Megan

Sent: Friday, February 07, 2020 1:36 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

How about this? Stacy and all – is this closer?

(b)(5)

(b)(5)

Megan McSeveney

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cel: (b)(6)

Megan.McSeveney@fda.hhs.gov



From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Friday, February 07, 2020 1:34 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy

<Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 7, 2020 at 1:03:54 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs

Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546



From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:01 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Megan McSeveney
Press Officer



From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:00 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

I am not sure we can get anywhere discussing among ourselves, but I can participate in a call if there is one.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:56 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Hi Stacy – I connected with Anna – I'll work with the group on this for the 20-30 min ahead of the presser and see what we can get. John, Don, Michael, Liz and Brad – maybe we can hop quickly on a call and discuss?

Megan McSeveney
Press Officer

Office of Media Affairs
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Megan.McSeveney@fda.hhs.gov



From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:52 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:50 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:49 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Here you go.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:46 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Dr. Hahn just asked to see his tps – do we have the other ones ready?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:33 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
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U.S. Food and Drug Administration
Tel: 240-402-4514/Celi (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 07, 2020 12:30 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Need ASAP. Thanks.

Sent from my iPhone

On Feb 7, 2020, at 12:11 PM, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov> wrote:

(b)(5)

and will send asap.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Friday, February 7, 2020 11:53 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)

Unfortunately, we need this asap

Thank you in advance

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/7/2020 6:06:04 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: RE: dont send SITREP yet
Attachments: 12_2019-nCoV Outbreak_FDA SITREP_07 February 2020.docx

Updated version

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 5:33 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: RE: dont send SITREP yet

Already sent, so we will have to send him updated when it comes in.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 7, 2020 5:32 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: dont send SITREP yet
Importance: High

Hi – don't send to Commish yet – CDRH tweaking – (b)(5) Will send in a few

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/7/2020 10:19:06 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]
Subject: FW: HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #66) - Senior Leadership Brief 2/7/2020
Attachments: ASPR SLB Tier 3 - 2019-nCoV 07Feb20.pdf

FYI- today's ASPR Senior Leader Brief for nCoV attached.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



From: Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>
Sent: Friday, February 7, 2020 10:10 PM
To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #66) - Senior Leadership Brief 2/7/2020

Fysa. Also find attached the most current Senior Leadership Brief - 2/7/2020.

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HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #66)

Source: HHS, CDC

What: As of 07Feb20, 31,479 cases of confirmed 2019-nCoV in 28 locations worldwide.

- As of 07Feb20, 20,333 travelers have been screened; 10 persons under mandatory 14-day quarantine. There are 12 confirmed cases in U.S. (1-Arizona, 1-Massachusetts, 6-California, 2-Illinois, 1-Washington, 1-Wisconsin).

Global Case Counts

- Total global confirmed cases = 31,479
- Total global confirmed deaths = 638

- New Cases (~24 hrs.) = **3,204**
- Countries with cases = 28

HHS Posture

- HHS SOC remains activated at Level 1 (24/7)
- HHS IMT personnel deployed to repatriation sites across U.S.
- CDC EOC remains activated (Agency Wide)

Russell Zablan

Interagency Information Liaison/RFI Lead

2019 Novel Coronavirus (nCoV) IMG

U.S. Food and Drug Administration

Desk: 404-253-2264

Cell: (b)(6)

Email: russell.zablan@fda.hhs.gov

IMG Planning Section email:

2019-nCoVFDAIMGPlanning@fda.hhs.gov

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/8/2020 8:44:14 AM
To: Ferro, Phil J. EOP/NSC (b)(6); MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
(b)(6) Yanick, Brittany M. EOP/WHO (b)(6) Browne, Lisa Y.
EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov]; DL NSC Legislative
(b)(6) Lowry, Patrick J. EOP/NSC (b)(6) Redfield, Robert R (CDC)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Gulati, Neetu
(b)(6) Bain, Ally P. EOP/OMB (b)(6) Cavanaugh, Brian J. EOP/NSC
(b)(6) Firoved, Aaron (b)(6) Hudson, Renee R. EOP/WHO
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Carlson, Eric J (b)(6) Lattimore, Tracie B. EOP/OSTP (b)(6)
 amie.kalsbeek@dot.gov; Waterman, Paige E. EOP/OSTP (b)(6) Kerr, Lawrence (OS)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Watson, Ian D.
EOP/OSTP (b)(6) Tobin, Elizabeth D. EOP/NSC (b)(6) Planning,
David M. EOP/WHO (b)(6) Burris, Meghan K. EOP/WHO
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(b)(6) Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-icb3-cd]; Hayes, Bradley F.
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Campana, Alexandra D. EOP/WHO (b)(6) Redd, John T (OS)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Davis, May M. EOP/WHO
(b)(6) Thallam, Satya P. EOP/OMB (b)(6) Troye, Olivia EOP/NSC
(b)(6) Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Thomas, Gloria D (OS)
 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b24779f604deb26d8a2e5-HHS-Gloria.]; Frater, Eric M
(b)(6) McMillin, Virginia D. EOP/WHO (b)(6) Boney, Virginia M.
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Sefel, Gary A. EOP/NSC
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.];
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 [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; DL NSC STRATCOM
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[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcedd4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; Tully, Ryan M.
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Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Wong, Anna W.
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; donna.o'berry@dot.gov;
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Limage, Julia; (b)(6) Baehr, James S. EOP/WHO (b)(6) DL NSC WMD
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Burton, Nicholas S.
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OSD OUSD POLICY (USA) (b)(6) Sinclair, Michael R. EOP/NSC
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(b)(6) Bailey, Drew M. EOP/OMB (b)(6) Disbrow, Gary (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Henning, Alexa A.
EOP/WHO (b)(6) Kanapathy, Ivan J. EOP/NSC (b)(6)

CC: Curtis, Lisa A. EOP/NSC (b)(6); Hallisey, William B. EOP/NSC
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(b)(6) Reilly, Tom M. EOP/OMB (b)(6) Blue, Matthew (ODAG
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(b)(6) JACKSTA, LINDA L (b)(6) FORET, VERNON T
(b)(6) Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Ellis, Michael J.
EOP/WHO (b)(6) Beaumont, Taylor W (b)(6) Walsh, Erin E. EOP/NSC
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(b)(6) Galkowski, James J. EOP/WHO (b)(6) Scott Tatlock
[Scott.Tatlock@trade.gov]; Havranek, John (b)(6) Ash, Deborah J. EOP/NSC
(b)(6); Iltebir, Elnigar EOP/NSC (b)(6)

Subject: nCoV Daily (b)(5)
Attachments: nCoV (b)(5) Agenda_Jan31.docx
Location: ***UPDATED LOCATION*** EEOB Room 374 SMS Large
Start: 1/31/2020 9:00:00 AM
End: 1/31/2020 10:30:00 AM
Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

Please accept this invite to attend a daily nCoV (b)(5)
SVTC. Due to space constraints we ask that Departments, Agencies as well as EOP components please send the
minimum number of participants. Accordingly, individuals attending this meeting must have the authority to speak on
the behalf of their organization. (b)(5)
(b)(5) As we
establish a battle rhythm for the meetings and the situation continues to evolve the composition and execution may
change.

Please use the WAVES link to register for attendance. (b)(6)

Best Regards,

Phil

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/9/2020 5:26:38 PM
To: Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Thompson, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45bad77196f04331af573e6be45be08b-Lori.Thomps]
Subject: FYI- Today's ASPR Senior Leader Brief and International SPOTREP: Novel Coronavirus, Wuhan, China
Attachments: ASPR SLB nCoV 09Feb20 - 1700.pdf

For awareness- today's ASPR nCoV Senior Leader Brief attached, and SPOTREP info below; received from internal FDA IMG distribution.

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HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #72)

Source: HHS, CDC

What: As of **09Feb20**, **37,553** cases of confirmed 2019-nCoV in 28 locations worldwide.

- The Japanese Ministry of Health , Labor and Welfare has confirmed 6 additional cases of 2019-nCoV among the passengers on the cruise Ship Diamond Princess
- Testing for 336 passengers and crew has been completed with 70 confirmed cases of 2019-nCoV
- Among those cases 14 are American citizens

Global Case Counts

- Total global confirmed cases = **37,553**
- Total global confirmed deaths = **813**
- New Cases (~24 hrs.) = **2,680**
- Countries with cases = 28

HHS Posture

- HHS SOC remains activated at Level 1 (24/7)
- HHS IMT personnel deployed to repatriation sites across U.S.
- CDC EOC remains activated (Agency Wide)

For more details, please see attached HHS SLB for Novel Coronavirus which includes the **09Feb20** CDC SITREP for Novel Coronavirus.

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/9/2020 9:16:21 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: As Deaths Mount, China Tries to Speed Up Coronavirus Testing

<https://www.nytimes.com/2020/02/09/world/asia/china-coronavirus-tests.html>

In Hubei, it takes hours for samples to be sent to the laboratories and days for the results to be issued. The local health department says the labs can run 6,000 tests a day, but even with staff working around the clock, there aren't enough laboratories to keep up with the workload. The province is seeking outside help.

More crucially, Hubei is running short of testing kits and reagents. Only seven manufacturers have government approval to make test kits for the coronavirus. Their employees have been working overtime to deliver the kits, according to local news reports. More newly developed testing kits are in the pipeline, but it is unclear when they will be ready for use.

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:27:16 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense; DL NSC Legal; DL NSC NSA FO Staff; DL NSC STRATCOM; Droegemeier, Kelvin K. EOP/OSTP; Daravi, Kamran S. EOP/WHO; Grewe, Brenda L. EOP/NSC; Deere, Judd P. EOP/WHO; Ditto, Jessica E. EOP/WHO; Yanick, Brittany M. EOP/WHO; Hayes, Bradley F. EOP/OMB; Smith, Gregory L. EOP/WHO; Imize@usaid.gov; Gastfriend, Daniel Z. EOP/OMB; Baum, Kristina R. EOP/OSTP; Bicket, Mark C. EOP/OSTP; Blair, Robert B. EOP/WHO; Bonyun, Sean C. EOP/OSTP; Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; Grogan, Joseph J. EOP/WHO; Hudson, Renee R. EOP/WHO; Jack, Brian T. EOP/WHO; Kan, Derek T. EOP/OMB; Kratsios, Michael J. EOP/OSTP; Lattimore, Tracie B. EOP/OSTP; Lin, Merry S. EOP/WHO; McKenna, Michael A. EOP/WHO; Merkel, Theo W. EOP/WHO; Miles, Aaron R. EOP/OSTP; Olmem, Andrew J. EOP/WHO; Pataki, Tim A. EOP/WHO; Ray, Paul J. EOP/OMB; Wong, Anna W. EOP/CEA; Walters, William; Bonner, Maria K. EOP/WHO; Sinclair, Michael R. EOP/NSC; DL NSC WMD; Cetron, Martin (CDC); gary.c.rasicot@hq.dhs.gov; amie.kalsbeek@dot.gov; Naar, Alex (FAA); Firoved, Aaron; Limage, Julia; Seffel, Gary A. EOP/NSC; Redfield, Robert R (CDC); Waterman, Paige E. EOP/OSTP; Waterman, Elijah J. EOP/NSC; Watson, Ian D. EOP/OSTP; Biles, Amber D CDR USN OSD OUSD POLICY (USA); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); Marks, Peter; Mair, Michael; Kadlec, Robert P (OS); Kerr, Lawrence (OS); Grigsby, Garrett G (OS); Disbrow, Gary (OS); Tobert, Gwen M; Scovitch, Joseph R; Costello, Kelly E; DL NSC IO; DL NSC Asia; DL NSC Press; DL NSC Resilience; DL NSC HSA FO Staff; DL NSC Legislative; DL NSC BATS; Redd, John T (OS); Cornett, Elizabeth A CIV (USA); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA); Gulati, Neetu; Liebschutz, Jennifer E. EOP/OMB; Farquharson, Christine E. EOP/OMB; jslotnick@usaid.gov; Kendra Chittenden; Boney, Virginia M. EOP/WHO; Tully, Ryan M. EOP/NSC; Frater, Eric M; Christ, Katelyn E. EOP/NSC; Weinberger, Collin (OS); Landrum, Ryan P. EOP/NSC; Rault, Nick M. EOP/NSC; Hanna, Cory M. EOP/NSC; Burton, Nicholas S. EOP/OMB; Garufi, Marc A. EOP/OMB; Mroz, Sara K. EOP/NSC; Wade, Dave S. EOP/NSC; Troye, Olivia EOP/NSC; Carlson, Eric J; McGowan, Robert K (CDC); Lowry, Patrick J. EOP/NSC; Cartin, Josh M. EOP/NSC; Kanapathy, Ivan J. EOP/NSC; Elvander, Erika (OS); Cavanaugh, Brian J. EOP/NSC; Bakewell, Richard A; Thomas, Gloria D (OS); Butler, Jay C (CDC); Bright, Rick (OS); Ruggiero, Anthony J. EOP/NSC; Brett Armstrong - D1R; paul.detitta@gsa.gov; Marwaha, Brianna C; Carstens, Virgil W; Hassell, David (OS); McMillin, Virginia D. EOP/WHO; Telle, Adam R. EOP/WHO; Sugarman, AJ J. EOP/WHO; Planning, David M. EOP/WHO; Feddersen, Brett (FAA); Padget, Larry G; Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov); Baehr, James S. EOP/WHO; Magrino, Christopher; debbie.w.seguin (b)(6) william.ferrara (b)(6) Tobin, Elizabeth D. EOP/NSC; Jonas, Seth H. EOP/NSC; Martin, Gregory J; Music, Chris G. EOP/OMB; Ali, Nausher; Burris, Meghan K. EOP/WHO; Henning, Alexa A. EOP/WHO; Daravi, Roma S. EOP/WHO; Horstman, John H. EOP/WHO; MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA); Wilson, John Mark M. EOP/NSC; Martin, Michael E. EOP/NSC; donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC; Gray, Alexander B. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Stahlman, James E CIV OSD OUSD POLICY (USA); Ullyot, John L. EOP/NSC; Stufft, Julie M. EOP/NSC; Doster, Kim M. EOP/OSTP; Stimson, Brian (OS); Browne, Lisa Y. EOP/NSC; Davis, May M. EOP/WHO; Lekan, Scott M (ACF); Chafin, Kelly B. EOP/NSC; Bailey, Drew M. EOP/OMB; Thallam, Satya P. EOP/OMB; Allen, Ronald G. EOP/NSC; Schuchat, Anne (CDC); Bain, Ally P. EOP/OMB; Schmoyer, Michael (OS); Lepore, Loretta A (CDC); alexandra.doumas@usdoj.gov; Hinton, Denise; Champagne, Joshua D. EOP/NSC; Mesquita, Mario M; Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA); DL Chief of Staff Office; Ash, Deborah J. EOP/NSC; Reilly, Tom M. EOP/OMB; Havranek, John; Dumm, Christopher M; FORET, VERNON T; Ellis, Michael J. EOP/WHO; Blue, Matthew (ODAG); Decker, Matthew G. EOP/NSC; JACKSTA, LINDA L; Parra, Yolanda A; Carter, Hillary H. EOP/NSC; Galkowski, James J. EOP/WHO; Tokumasu de Silva, Miriam E; Doyle, Emma K. EOP/WHO; Lason, Adam J. EOP/NSC; Hemme, Jake W. EOP/NSC; Maycock, Brett (OS); owenre (b)(6) Miller, James N

Subject: nCoV Daily (b)(5)
Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30 (b)(5) Agenda.docx
Location: Updated Location - WHSR JFK
Start: 2/17/2020 9:00:00 AM
End: 2/17/2020 10:30:00 AM
Show Time As: Tentative

Dear Colleagues,

To avoid unnecessary confusion, I will send out invites for individual meetings as they are needed and cancel this series.

Best,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:27:34 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6);
(b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee K. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Odf896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rascot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Sefel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6)

(b)(6) Frater, Eric M (b)(6) Christ, Katelyn E. EOP/NSC
(b)(6); Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Wade, Dave S.
EOP/NSC (b)(6) Troye, Olivia EOP/NSC (b)(6) Carlson, Eric J
(b)(6) McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J.
EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
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paul.detitta@gsa.gov; Marwaha, Brianna C (b)(6) Carstens, Virgil W (b)(6)
Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Sugarman,
AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6)
Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S.
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(b)(6) Magrino, Christopher (b)(6)
debbie.w.seguin (b)(6) william.ferrara (b)(6) Tobin, Eliza beth D. EOP/NSC
(b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J
(b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6)
Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO
(b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John
H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
(b)(6) Wilson, John Mark M. EOP/NSC (b)(6) Martin, Michael
E. EOP/NSC (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC
(b)(6); Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
EOP/NSC (b)(6) Stahlman, James E CIV OSD OUSD POLICY (USA)
(b)(6) Ulyot, John L. EOP/NSC (b)(6) Stuftt, Julie M. EOP/NSC
(b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fc1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6) Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya
P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acsl-cd]; Bain, Ally P. EOP/OMB
(b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office
(b)(6) Leary, Thomas F. EOP/NSC (b)(6) Biery, Meghan N.
EOP/NSC (b)(6)

CC: Havranek, John (b)(6); Dumm, Christopher M (b)(6); FORET, VERNON T
(b)(6); Ellis, Michael J. EOP/WHO (b)(6); Blue, Matthew
(ODAG) [Matthew.Blue@usdoj.gov]; Ash, Deborah J. EOP/NSC (b)(6); Decker, Matthew G.
EOP/NSC (b)(6); JACKSTA, LINDA L (b)(6); Parra, Yolanda A
(b)(6); Reilly, Tom M. EOP/OMB (b)(6); Carter, Hillary H. EOP/NSC
(b)(6); Galkowski, James J. EOP/WHO (b)(6); Tokumasu de
Silva, Miriam E (b)(6); Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam
J. EOP/NSC (b)(6); Hemme, Jake W. EOP/NSC (b)(6); Maycock,
Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M]; owenre (b)(6)
Miller, James N (b)(6)

Subject: nCoV Daily (b)(5)
Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30 (b)(5) Agenda.docx
Location: Updated Location - WHSR JFK
Start: 2/12/2020 9:00:00 AM
End: 2/12/2020 10:30:00 AM
Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

Please accept this invite to attend a daily nCoV (b)(5). With exception of CDC Atlanta, NIAD and FDA there will be no SVTC. Due to space constraints we ask that Departments, Agencies as well as EOP components please send the minimum number of participants. Accordingly, individuals attending this meeting must have the authority to speak on the behalf of their organization. The intent is to ensure we are all receiving the same information and delivering a cohesive and unified preparedness and response effort as well as providing solutions and options to leadership. As we establish a battle rhythm for the meetings and the situation continues to evolve the composition and execution may change.

Please use the WAVES link to register for attendance: (b)(6)

Best Regards,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:27:34 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHC (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHC (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R. (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2b83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden (b)(6); Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6)

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(b)(6) ; Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Wade, Dave S.
EOP/NSC (b)(6) Troye, Olivia EOP/NSC (b)(6) Carlson, Eric J
(b)(6) McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov];
paul.detitta@gsa.gov; Marwaha, Brianna G (b)(6) Carstens, Virgil W (b)(6)
Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D.
EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Sugarman,
AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6)
Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S.
(GH/HIDN) [USAID] [rgreene@usaid.gov] [rgreene@usaid.gov]; Baehr, James S. EOP/WHO
(b)(6) Magrino, Christopher (b)(6)
debbie.w.seguin (b)(6) william.ferrara (b)(6) Tobin, Elizabeth D. EOP/NSC
(b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J
(b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6)
Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO
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(b)(6) Wilson, John Mark M. EOP/NSC (b)(6) Martin, Michael
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(b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
EOP/NSC (b)(6) Stahlman, James E CIV OSD OUSD POLICY (USA)
(b)(6) Ulyyot, John L. EOP/NSC (b)(6) Stufft, Julie M. EOP/NSC
(b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fc1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6) Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6) Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya
P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB
(b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office
(b)(6) Leary, Thomas F. EOP/NSC (b)(6) Biery, Meghan N.
EOP/NSC (b)(6)

CC: Havranek, John (b)(6); Dumm, Christopher M (b)(6); FORET, VERNON T (b)(6); Ellis, Michael J. EOP/WHO (b)(6); Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; Ash, Deborah J. EOP/NSC (b)(6); Decker, Matthew G. EOP/NSC (b)(6); JACKSTA, LINDA L (b)(6); Parra, Yolanda A (b)(6); Reilly, Tom M. EOP/OMB (b)(6); Carter, Hillary H. EOP/NSC (b)(6); Galkowski, James J. EOP/WHO (b)(6); Tokumasu de Silva, Miriam E (b)(6); Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam J. EOP/NSC (b)(6); Hemme, Jake W. EOP/NSC (b)(6); Maycock, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M]; owenre (b)(6); Miller, James N (b)(6)

Subject: Canceled: Canceled: nCoV Daily (b)(5)
Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30 (b)(5) agenda.docx
Location: Updated Location - WHSR JFK
Start: 2/12/2020 9:00:00 AM
End: 2/12/2020 10:30:00 AM
Show Time As: Free
Importance: High
Recurrence: (none)

Dear Colleagues,

Please accept this invite to attend a daily nCoV (b)(5). With exception of CDC Atlanta, NIAD and FDA there will be no SVTC. Due to space constraints we ask that Departments, Agencies as well as EOP components please send the minimum number of participants. Accordingly, individuals attending this meeting must have the authority to speak on the behalf of their organization. The intent is to ensure we are all receiving the same information and delivering a cohesive and unified preparedness and response effort as well as providing solutions and options to leadership. As we establish a battle rhythm for the meetings and the situation continues to evolve the composition and execution may change.

Please use the WAVES link to register for attendance.

(b)(6)

Best Regards,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:27:57 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6);
Daravi, Kamran S. EOP/WHO (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6);
Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6);
Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6);
Smith, Gregory L. EOP/WHO (b)(6); Imize@usaid.gov; Gastfriend, Daniel Z. EOP/OMB (b)(6);
Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6);
Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6);
Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6);
Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6);
Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6);
Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6);
Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6);
Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6);
Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Odf896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd];
gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6);
Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R. (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd];
Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6);
Biles, Amber D. CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S. (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-];
Marston, Hilary D. (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.];
Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP];
Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai];
Kadlec, Robert P. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.];
Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc];
Grigsby, Garrett G. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett];
Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di];
Tobert, Gwen M. (b)(6); Scovitch, Joseph R. (b)(6); Costello, Kelly E. (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6);
Redd, John T. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re];
Cornett, Elizabeth A. CIV (USA) (b)(6); Thornton, Cody R. CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6);
Farquharson, Christine E. EOP/OMB (b)(6); Boney, Virginia M. EOP/WHO (b)(6); jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Tully, Ryan M. EOP/NSC (b)(6)

(b)(6) Frater, Eric M (b)(6) Christ, Katelyn E. EOP/NSC
(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
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J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
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EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov];
paul.detitta@gsa.gov; Marwaha, Brianna C (b)(6) Carstens, Virgil W (b)(6)
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(b)(6) Magrino, Christopher (b)(6)
debbie.w.seguin (b)(6) william.ferrara (b)(6); Tobin, Elizabeth D. EOP/NSC
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(b)(6) Doster, Kim M. EOP/OSTP (b)(6) Stimson, Brian (OS)
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P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
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A (Chris) CTR OSD OUSD POLICY (USA) (b)(6); DL Chief of Staff Office
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CC: Ash, Deborah J. EOP/NSC (b)(6) Reilly, Tom M. EOP/OMB
(b)(6); Havranek, John (b)(6) Dumm, Christopher M
(b)(6) FORET, VERNON T (b)(6) Ellis, Michael J. EOP/WHO
(b)(6) Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC
(b)(6) JACKSTA, LINDA L (b)(6); Parra, Yolanda A
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(b)(6) Tokumasu de Silva, Miriam E (b)(6) Doyle, Emma K.
EOP/WHO (b)(6) Lason, Adam J. EOP/NSC (b)(6) Hemme, Jake W.
EOP/NSC (b)(6) Maycock, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M];
owenre (b)(6) Miller, James N (b)(6)

Subject: nCoV Daily (b)(5)
Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30 (b)(5) Agenda.docx
Location: Updated Location - WHSR JFK
Start: 2/17/2020 9:00:00 AM
End: 2/17/2020 10:30:00 AM
Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

To avoid unnecessary confusion, I will send out invites for individual meetings as they are needed and cancel this series.

Best,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:27:57 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHC (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC [Gary.A. (b)(6); Redfield, Robert R. (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D. CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S. (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D. (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M. (b)(6); Scovitch, Joseph R. (b)(6); Costello, Kelly E. (b)(6); DL NSC ID: (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A. CIV (USA) (b)(6); Thornton, Cody R. CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

[kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6) Tully, Ryan M. EOP/NSC
(b)(6) Frater, Eric M (b)(6) Christ, Katelyn E. EOP/NSC
(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6); Mroz, Sara K. EOP/NSC (b)(6) Wade, Dave S.
EOP/NSC (b)(6); Troye, Olivia EOP/NSC (b)(6) Carlson, Eric J
(b)(6) McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J.
EOP/NSC (b)(6); Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
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Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D.
EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Sugarman,
AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6)
Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S.
(GH/HIDN) [USAID] [rgreene@usaid.gov] [rgreene@usaid.gov]; Baehr, James S. EOP/WHO
(b)(6) Magrino, Christopher (b)(6)
debbie.wseguin (b)(6) william.ferrara (b)(6) robin, Elizabeth D. EOP/NSC
(b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J
(b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6)
Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO
(b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John
H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
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E. EOP/NSC (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC
(b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
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(b)(6) Ulliyot, John L. EOP/NSC (b)(6) Stuftt, Julie M. EOP/NSC
(b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6); Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6) Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya
P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB
(b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office

(b)(6) Leary, Thomas F. EOP/NSC (b)(6); Biery, Meghan N.
EOP/NSC (b)(6)
CC: Ash, Deborah J. EOP/NSC (b)(6) Reilly, Tom M. EOP/OMB
(b)(6) Havranek, John (b)(6) Dumm, Christopher M
(b)(6) FORET, VERNON T (b)(6) Ellis, Michael J. EOP/WHO
(b)(6) Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC
(b)(6) JACKSTA, LINDA L (b)(6) Parra, Yolanda A
(b)(6) Carter, Hillary H. EOP/NSC (b)(6) Galkowski, James J. EOP/WHO
(b)(6) Tokumasu de Silva, Miriam E (b)(6) Doyle, Emma K.
EOP/WHO (b)(6) Lason, Adam J. EOP/NSC (b)(6) Hemme, Jake W.
EOP/NSC (b)(6) Maycock, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3addee42-HHS-Brett.M];
owenre (b)(6); Miller, James N (b)(6)

Subject: Canceled: Canceled: nCoV Daily (b)(5)
Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30 (b)(5) Agenda.docx
Location: Updated Location - WHSR JFK

Start: 2/14/2020 9:00:00 AM
End: 2/14/2020 10:30:00 AM
Show Time As: Free
Importance: High
Recurrence: (none)

Dear Colleagues,

Please accept this invite to attend a daily nCoV (b)(5). With exception of CDC Atlanta, NIAD and FDA there will be no SVTC. Due to space constraints we ask that Departments, Agencies as well as EOP components please send the minimum number of participants. Accordingly, individuals attending this meeting must have the authority to speak on the behalf of their organization. The intent is to ensure we are all receiving the same information and delivering a cohesive and unified preparedness and response effort as well as providing solutions and options to leadership. As we establish a battle rhythm for the meetings and the situation continues to evolve the composition and execution may change.

Please use the WAVES link to register for attendance (b)(6)

Best Regards,

Phil

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 2/10/2020 10:27:57 AM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: China Inspections Tear Sheet--AMA

Yes feel free to add to the document, thank you!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Monday, February 10, 2020 10:25 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Hi all - no edits from me (b)(5)

(b)(5)

(b)(5) I am still catching up on email after a weekend away so apologies if I am being duplicative but, the JIC knows about this request and we will be checking with IMG to make sure the information is up to date (b)(5)

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Monday, February 10, 2020 9:50 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Attached here. Stacy, (b)(5)
(b)(5) Any edits are appreciated. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 9:45 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Karas, please share with Stacy. Adding her here.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: February 9, 2020 at 10:12:58 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Thanks, Anna.

If anyone else has edits, please let me know by 10am (or let me know that you need more time).

Megan, (b)(5) Asking in case ASL asks for another update. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 9, 2020 at 9:25:33 PM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

My laptop is finally working now so I was able to make some edits (b)(5)

(b)(5)

See attached.

Internal confidential

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Saturday, February 8, 2020 8:13 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: China Inspections Tear Sheet--AMA

Internal, confidential, pre-decisional

Hi Anna and Keagan-

(b)(5)

Once you all review and are in a good place, I can share these with Laura.

Thanks!
Karas

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:28:11 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasiot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbddd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchitte nden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6)

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(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Wade, Dave S.
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EOP/NSC (b)(6) Martin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
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(b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6)
Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO
(b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John
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[francesca.c.music2.civ@mail.mil]; Wilson, John Mark M. EOP/NSC (b)(6) Martin, Michael
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(b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
EOP/NSC (b)(6); Stahlman, James E CIV OSD OUSD POLICY (USA)
(b)(6) Ulyot, John L. EOP/NSC (b)(6) Stuftt, Julie M. EOP/NSC
(b)(6) Doster, Kim M. EOP/OSTP (b)(6) Stimson, Brian (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6) Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6) Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya
P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Bain, Ally P. EOP/OMB
(b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office
(b)(6)

CC: Havranek, John (b)(6); Dumm, Christopher M (b)(6); FORET, VERNON T (b)(6); Ellis, Michael J. EOP/WHO (b)(6); Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; Ash, Deborah J. EOP/NSC (b)(6); Decker, Matthew G. EOP/NSC (b)(6); JACKSTA, LINDA L (b)(6); Parra, Yolanda A (b)(6); Reilly, Tom M. EOP/OMB (b)(6); Carter, Hillary H. EOP/NSC (b)(6); Galkowski, James J. EOP/WHO (b)(6); Tokumasu de Silva, Miriam E (b)(6); Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam J. EOP/NSC (b)(6); Hemme, Jake W. EOP/NSC (b)(6); Maycock, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M]; owenre (b)(6); Miller, James N (b)(6)

Subject: nCoV Daily (b)(5)

Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30 (b)(5) Agenda.docx; Canceled: nCoV Daily (b)(5) Canceled: WCoV (b)(5)

Location: Updated Location - WHSR JFK

Start: 1/30/2020 9:00:00 AM

End: 1/30/2020 10:30:00 AM

Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

To avoid unnecessary confusion, I will send out invites for individual meetings as they are needed and cancel this series.

Best,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 10:28:11 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra DEOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Odf896abcedd4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R. (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S. (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D. (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M. (b)(6); Scovitch, Joseph R. (b)(6); Costello, Kelly E. (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Pres (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T. (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A. CIV (USA) (b)(6); Thornton, Cody R. CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6); Frater, Eric M. (b)(6); Christ, Katelyn E. EOP/NSC (b)(6)

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(b)(6); Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew
(ODAG) [Matthew.Blue@usdoj.gov]; Ash, Deborah J. EOP/NSC (b)(6) Decker, Matthew G.
EOP/NSC (b)(6); JACKSTA, LINDA L (b)(6); Parra, Yolanda A
(b)(6) Reilly, Tom M. EOP/OMB (b)(6) Carter, Hillary H. EOP/NSC
(b)(6); Galkowski, James J. EOP/WHO (b)(6) Tokumasu de
Silva, Miriam E (b)(6); Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam
J. EOP/NSC (b)(6) Hemme, Jake W. EOP/NSC (b)(6); Maycock,
Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M]; owenre (b)(6)
Miller, James N (b)(6)

Subject: Canceled: Canceled: nCoV Daily (b)(5)
Attachments: Canceled: nCoV Daily (b)(5) Canceled: Canceled: WCoV (b)(5) nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30
PCC Agenda.docx
Location: Updated Location - WHSR JFK
Start: 1/30/2020 9:00:00 AM
End: 1/30/2020 10:30:00 AM
Show Time As: Free
Importance: High
Recurrence: (none)

Dear Colleagues,

To avoid unnecessary confusion, I will send out invites for individual meetings as they are needed and cancel this series.

Best,

Phil

From: Raza, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5811A7D72EE34AA78FF3C8CCB59F92EE-MRAZA]
Sent: 2/10/2020 12:21:53 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; 2019-nCoV FDA IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1303ad17cce4c95b45c63ac5c0c31df-2019-nCoV F]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]
CC: Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1bf7cb4c1d287f83e-ChoD]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Jackson, LeeAnne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=736277c6fd7b486db5807177dc64a362-LJACKSO1]; Glover, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23fc3452dfd0414184cbb290047b7865-Mark.Glover]
Subject: RE: FOR URGENT REVIEW HHS/NSC REQUEST CORONAVIRUS - deadline 12:30pm TODAY

No comments from OCC. thanks

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 12:19 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>
Cc: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW HHS/NSC REQUEST CORONAVIRUS - deadline 12:30pm TODAY

I have edits will send when I can

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Date: February 10, 2020 at 12:06:34 PM EST

To: 2019-nCoV FDA IMG <2019-nCoVFDAlMG@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>

Cc: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Roberts, Rosemary <Rosemarv.Roberts@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>, Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>, Glover, Mark <Mark.Glover@fda.hhs.gov>

Subject: FOR URGENT REVIEW HHS/NSC REQUEST CORONAVIRUS - deadline 12:30pm TODAY

Hi all – we have a very short turnaround from NSC via HHS. Each HHS OpDiv is being asked to share bullets about our efforts during this coronavirus outbreak to date. Below and attached as FDABULLETSFORNSC is an initial draft. I need any edits/additions back by 12:30. I am sending this for concurrent review given the tight deadline. Thank you all!

(b)(5)

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>

Sent: Monday, February 10, 2020 11:37 AM

To: Bonds, Michelle E (CDC) <meb0@cdc.gov>; Haynes, Benjamin (CDC) <fxg2@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Heldman, Amy B (CDC) <evd4@cdc.gov>; Billet, Courtney R (NIH) <billetc@niaid.nih.gov>; Stover, Kathy A (NIH) <kathy.stover@nih.gov>; Routh, Jennifer M (NIH) <jennifer.routh@nih.gov>; Michael, Gretchen (OS) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS) <Elleen.Kane@hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Subject: URGENT— Fwd: NCOV Fact Sheet

Hi all,

NSC wants to pull together a fact sheet that summarizes key actions that the USG has taken to date as part of the coronavirus response. Can you all please send me **by 12:30 pm today** a bullet list of key actions your agency has taken?

Thanks
Bill

Sent from my iPhone

Begin forwarded message:

From: "Wilson, John Mark M. EOP/NSC" <(b)(6)>
Date: February 10, 2020 at 9:59:57 AM EST
To: "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>, "Hall, Bill (HHS/ASPA)" <bill.hall@hhs.gov>, "Michael, Gretchen (OS/ASPR/OEA)" <Gretchen.Michael@hhs.gov>, "BrownC4" <(b)(6)>, "BrownC4" <(b)(6)>, "Ortagus, Morgan D" <(b)(6)>, "Farah, Alyssa A SES (USA)" <(b)(6)>, "Hoffman, Jonathan R SES OSD OSD (USA)" <(b)(6)>
Cc: "Ullyot, John L. EOP/NSC" <(b)(6)>, "Martin, Michael E. EOP/NSC" <(b)(6)>
Subject: NCOV Fact Sheet

Colleagues

Short Suspense Action Follows—By 2:00pm today.

We are putting together a fact sheet for legislative and press engagement. NSC/WH have lead on its construction and Interagency clearance, but need building blocks from your specific agencies re: key actions undertaken to contain 2019 NCOV. Please send me a rollup of key facts or actions undertaken by your respective department agency by 1:00 pm today. Given the short fuse, recommend you draw from your existing material. To help, here is the most recent NCOV

PG and the Coronavirus Federal Funding Fact Sheet produced by OMB. You might be able to draw from these document as well.

Thanks

John Mark Wilson

Office of Strategic Communications

National Security Council

(b)(6)

Office: 202-456-9275

Cell: (b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/10/2020 12:30:16 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: MICHAEL - FOR URGENT REVIEW HHS/NSC REQUEST CORONAVIRUS - deadline 12:30pm TODAY

I know you're in a meeting so highlighting for you

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Monday, February 10, 2020 12:29 PM
To: Ross, Bruce <Bruce.Ross@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>
Cc: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW HHS/NSC REQUEST CORONAVIRUS - deadline 12:30pm TODAY

Thank you, Bruce. Anna – I know you have edits. Michael, will you have any edits? Thank you!

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Sent: Monday, February 10, 2020 12:26 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>
Cc: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW HHS/NSC REQUEST CORONAVIRUS - deadline 12:30pm TODAY

Bruce Ross, MA, MPH

Director, (Acting)

Office of Global Operations
Office of Global Policy and Strategy

Tel: 240-402-2866
Mobile: (b)(6)
E-mail: Bruce.Ross@fda.hhs.gov

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 12:07 PM

To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>

Cc: Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>

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(b)(5)

(b)(5)

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



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Sent: Monday, February 10, 2020 11:37 AM

To: Bonds, Michelle E (CDC) <meb0@cdc.gov>; Haynes, Benjamin (CDC) <fxq2@cdc.gov>; Galatas, Kate (CDC) <kkg2@cdc.gov>; Heldman, Amy B (CDC) <evd4@cdc.gov>; Billet, Courtney R (NIH) <billetc@niaid.nih.gov>; Stover, Kathy A (NIH) <kathy.stover@nih.gov>; Routh, Jennifer M (NIH) <jennifer.routh@nih.gov>; Michael, Gretchen (OS) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS) <Elleen.Kane@hhs.gov>; Rabin, Tara G. <Tara.Rabin@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>

Subject: URGENT— Fwd: NCOV Fact Sheet

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Sent from my iPhone

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From: "Wilson, John Mark M. EOP/NSC" <(b)(6)>

Date: February 10, 2020 at 9:59:57 AM EST

To: "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>, "Hall, Bill (HHS/ASPA)" <bill.hall@hhs.gov>, "Michael, Gretchen (OS/ASPR/OEA)" <Gretchen.Michael@hhs.gov>, "BrownC4" <(b)(6)>, "BrownC4" <(b)(6)>, "Ortagus, Morgan D" <(b)(6)>, "Farah, Alyssa A SES (USA)" <(b)(6)>, "Hoffman, Jonathan R SES OSD OSD (USA)" <(b)(6)>

Cc: "Ulliyot, John L. EOP/NSC" <(b)(6)>, "Martin, Michael E. EOP/NSC"

<(b)(6)>

Subject: NCOV Fact Sheet

Colleagues

Short Suspense Action Follows—By 2:00pm today.

We are putting together a fact sheet for legislative and press engagement. NSC/WH have lead on its construction and Interagency clearance, but need building blocks from your specific agencies re: key actions undertaken to contain 2019 NCOV. Please send me a rollup of key facts or actions undertaken by your respective department agency by 1:00 pm today. Given the short fuse, recommend you draw from your existing material. To help, here is the most recent NCOV PG and the Coronavirus Federal Funding Fact Sheet produced by OMB. You might be able to draw from these document as well.

Thanks

John Mark Wilson
Office of Strategic Communications
National Security Council

(b)(6)

Office: [202-456-9275](tel:202-456-9275)

Cell: (b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/10/2020 12:43:37 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]
Subject: For Action: Review RPD Strategy by COB Today
Attachments: USG Roadmap to Extend RPD Supply _Draft 021020.docx
Importance: High

Just seeing this as I catch up on emails – thanks!

From: Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>
Sent: Monday, February 10, 2020 11:13 AM
To: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Alexandre, Gwendolyn (OS) <Gwendolyn.Alexandre@hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kovacs, Gerald (OS) <Gerald.Kovacs@hhs.gov>; Angelastro, Michael (OS) <Michael.Angelastro@hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Ottem, Ronald S (CDC) <rco9@cdc.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Subject: For Action: Review RPD Strategy by COB Today

Good morning all,

As Laura mentioned on the call, please see the attached document for review by COB today. Please send any comments to me for compilation by 5pm.

Thanks,
Brittney

Brittney Seiler

U.S. Department of Health & Human Services
Assistant Secretary for Preparedness & Response (ASPR)
Office: 202-205-9717
Cell: 202-731-6583
Brittney.seiler@hhs.gov

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Monday, February 10, 2020 9:06 AM
To: Hinton, Denise (FDA/OC) <Denise.Hinton@fda.hhs.gov>; Alexandre, Gwendolyn (OS/ASPR/SIIM) (CTR) <Gwendolyn.Alexandre@hhs.gov>; Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Kovacs, Gerald (OS/ASPR/BARDA) (CTR) <Gerald.Kovacs@hhs.gov>; Angelastro, Michael (OS/ASPR/BARDA) <Michael.Angelastro@hhs.gov>; Patel, Paras M (FDA/CDER) <Paras.Patel@fda.hhs.gov>; Ottem, Ronald (Ron) (CDC/SNS/DSNS) <rco9@cdc.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>; Cooper, Kevin (OS/ASPR/ORM) <Kevin.Cooper@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>
Subject: Touch base on supply chain at 10

Hello all-

As we all reformulate our strategy on supply chain post-DLG, I wanted to have a session specifically on a data- I want to explain what dr Kadlec is asking us for and what you all are doing so we can coordinate. There is an overall strategy and a specific White House ask to discuss. Assuming you all still have the 10am slot since we cancelled the task force meeting for that time. Gwen will send an invite.

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR

Unclassified: Laura.wolf@hhs.gov

HSDN: Laura.wolf@dhs.gov

Desk

Cell

(b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/10/2020 5:09:35 PM
To: Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Tarver, Darian B. [Darian.Tarver@fda.hhs.gov]; Nabakowski, Andrei [Andrei.Nabakowski@fda.hhs.gov]; Anderson, Randy [Randy.Anderson@fda.hhs.gov]
Subject: FYSA: FDA 2019-nCOV SITREP - 10 Feb 2020
Attachments: 13_2019-nCoV Outbreak_FDA SITREP_10 February 2020.docx

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, February 10, 2020 5:08 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Subject: FDA 2019-nCOV SITREP - 10 Feb 2020

Hi,

Attached for your situational awareness is the 10 February FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support. -Michael

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/10/2020 7:32:19 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense; DL NSC Legal; DL NSC NSA FO Staff; DL NSC STRATCOM; Droegemeier, Kelvin K. EOP/OSTP; Daravi, Kamran S. EOP/WHO; Grewe, Brenda L. EOP/NSC; Deere, Judd P. EOP/WHO; Ditto, Jessica E. EOP/WHO; Yanick, Brittany M. EOP/WHO; Hayes, Bradley F. EOP/OMB; Smith, Gregory L. EOP/WHO; Doster, Kim M. EOP/OSTP; Gastfriend, Daniel Z. EOP/OMB; Baum, Kristina R. EOP/OSTP; Bicket, Mark C. EOP/OSTP; Blair, Robert B. EOP/WHO; Bonyun, Sean C. EOP/OSTP; Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; Grogan, Joseph J. EOP/WHO; Hudson, Renee R. EOP/WHO; Jack, Brian T. EOP/WHO; Kan, Derek T. EOP/OMB; Kratsios, Michael J. EOP/OSTP; Lattimore, Tracie B. EOP/OSTP; Lin, Merry S. EOP/WHO; McKenna, Michael A. EOP/WHO; Merkel, Theo W. EOP/WHO; Miles, Aaron R. EOP/OSTP; Olmem, Andrew J. EOP/WHO; Pataki, Tim A. EOP/WHO; Ray, Paul J. EOP/OMB; Wong, Anna W. EOP/CEA; Walters, William; Bonner, Maria K. EOP/WHO; Sinclair, Michael R. EOP/NSC; DL NSC WMD; Cetron, Martin (CDC); gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA); Firoved, Aaron; Limage, Julia; Seffel, Gary A. EOP/NSC; Redfield, Robert R (CDC); Waterman, Paige E. EOP/OSTP; Waterman, Elijah J. EOP/NSC; Watson, Ian D. EOP/OSTP; Biles, Amber D CDR USN OSD OUSD POLICY (USA); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); Marks, Peter; Mair, Michael; Kadlec, Robert P (OS); Kerr, Lawrence (OS); Grigsby, Garrett G (OS); Disbrow, Gary (OS); Tobert, Gwen M; Scovitch, Joseph R; Costello, Kelly E; DL NSC IO; DL NSC Asia; DL NSC Press; DL NSC Resilience; DL NSC HSA FO Staff; DL NSC Legislative; DL NSC BATS; Redd, John T (OS); Cornett, Elizabeth A CIV (USA); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA); Gulati, Neetu; Liebschutz, Jennifer E. EOP/OMB; Farquharson, Christine E. EOP/OMB; Imize@usaid.gov; jslootnick@usaid.gov; Kendra Chittenden; Boney, Virginia M. EOP/WHO; Tully, Ryan M. EOP/NSC; Frater, Eric M; Christ, Katelyn E. EOP/NSC; Weinberger, Collin (OS); Landrum, Ryan P. EOP/NSC; Rault, Nick M. EOP/NSC; Hanna, Cory M. EOP/NSC; Burton, Nicholas S. EOP/OMB; Garufi, Marc A. EOP/OMB; Mroz, Sara K. EOP/NSC; Wade, Dave S. EOP/NSC; Troye, Olivia EOP/NSC; Carlson, Eric J; McGowan, Robert K (CDC); Lowry, Patrick J. EOP/NSC; Cartin, Josh M. EOP/NSC; Kanapathy, Ivan J. EOP/NSC; Elvander, Erika (OS); Cavanaugh, Brian J. EOP/NSC; Bakewell, Richard A; Thomas, Gloria D (OS); Butler, Jay C (CDC); Bright, Rick (OS); Ruggiero, Anthony J. EOP/NSC; Brett Armstrong - D1R; paul.detitta@gsa.gov; Marwaha, Brianne C; Carstens, Virgil W; Hassell, David (OS); McMillin, Virginia D. EOP/WHO; Telle, Adam R. EOP/WHO; Sugarman, AJ J. EOP/WHO; Planning, David M. EOP/WHO; Feddersen, Brett (FAA); Padget, Larry G; Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov); Baehr, James S. EOP/WHO; Magrino, Christopher; debbie.w.seguin (b)(6); william.ferrara (b)(6); Tobin, Elizabeth D. EOP/NSC; Jonas, Seth H. EOP/NSC; Martin, Gregory J; Music, Chris G. EOP/OMB; Ali, Nausher; Burris, Meghan K. EOP/WHO; Henning, Alexa A. EOP/WHO; Daravi, Roma S. EOP/WHO; Horstman, John H. EOP/WHO; MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA); Wilson, John Mark M. EOP/NSC; Martin, Michael E. EOP/NSC; donna.o.berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC; Gray, Alexander B. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Stahlman, James E CIV OSD OUSD POLICY (USA); Ulylot, John L. EOP/NSC; Stufft, Julie M. EOP/NSC; Stimson, Brian (OS); Browne, Lisa Y. EOP/NSC; Davis, May M. EOP/WHO; Lekan, Scott M (ACF); Chafin, Kelly B. EOP/NSC; Bailey, Drew M. EOP/OMB; Thallam, Satya P. EOP/OMB; Allen, Ronald G. EOP/NSC; Schuchat, Anne (CDC); Bain, Ally P. EOP/OMB; Schmoyer, Michael (OS); Lepore, Loretta A (CDC); alexandra.doumas@usdoj.gov; Hinton, Denise; Champagne, Joshua D. EOP/NSC; Mesquita, Mario M; Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA); DL Chief of Staff Office; (b)(6); (b)(6); Ash, Deborah J. EOP/NSC; Reilly, Tom M. EOP/OMB; Havranek, John; Dumm, Christopher M; FORET, VERNON T; Ellis, Michael J. EOP/WHO; Blue, Matthew (ODAG); Decker, Matthew G. EOP/NSC; JACKSTA, LINDA L; Parra, Yolanda A; Carter, Hillary H. EOP/NSC; Galkowski, James J. EOP/WHO; Tokumasu de Silva, Miriam E; Doyle, Emma K. EOP/WHO; Lason, Adam J. EOP/NSC; McPheeME (b)(6); Carson, Tracy L (Geneva); Bibo, David

Subject: WCoV (b)(5)
Attachments: Phases of USG nCoV Response_COORD.docx
Location: EEOB Room 445 Please submit WAVES for each meeting
Start: 2/11/2020 10:30:00 AM
End: 2/11/2020 12:00:00 PM
Show Time As: Tentative
Importance: High

Dear Colleagues,

The WHTF has directed the (b)(5) The document that will be developed by the (b)(5) over the next 36 hours will be discussed by the WHTF during their in-person meeting on Wednesday. SAP Ruggiero will convene a WCoV PCC tomorrow to develop the aforementioned document. You will find attached a first draft of the framework. The expectation is that D/A will come to the meeting prepared to discuss the overarching framework as well as to provide (in writing) the contributions, roles and responsibilities of their D/A.

It is expected that all D/A will work closely with agency counsel to ensure that you have the legal authority to implement each specific action. Do not include an action if you are unsure of the underlying authority and expressly note where further legal analysis is necessary to determine the scope or breadth of an authority, if you are uncertain as to its scope or breadth.

The sole purpose of the meeting tomorrow will be to build out this document. The classification of this meeting will be U//FOUO.

Participants are expected to attend in person. With exception of CDC Atlanta and NIAD any SVTC connection will be in listen only mode, though D/A are welcome to have additional participants listen in via SVTC for SA. Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization. FYSA, you will also see an invite for another PCC tomorrow from 1500-1600 in case it is needed as well as an invite for Wednesday morning.

Please use the WAVES link to register for attendance. (b)(6)

Best Regards,

Phil

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/10/2020 9:04:23 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
Subject: RE: China Inspections Tear Sheet--AMA

Thank you, Megan!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Monday, February 10, 2020 7:59 PM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Hi – to follow up on my earlier note – I'll make edits to both these attachments as necessary and will continue to coordinate with Prakash. Thanks and apologies for any confusion! 😊

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: McSeveney, Megan

Sent: Monday, February 10, 2020 7:43 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi Karas – thank you for your note. I am looking at the attachment and can make those edits there if necessary. If there are other documents we should edit that I may not have or if I can help in any other way please let me know. Also, wanted to thank and share how great it has been working with Prakash, Caitlin, and everyone at OL – the ability to divide and conquer information requests has helped to keep messaging consistent and is greatly appreciated! Best, M

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 7:37 PM

To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Thanks for tracking this down. Can you please make the appropriate edits based on these comments. Thanks!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Sent: Monday, February 10, 2020 7:32 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Adding Mark

From: Rath, Prakash (FDA)

Sent: Monday, February 10, 2020 7:31 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

(b)(5)

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 3:42 PM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Thank you!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 3:42 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Hi Karas – [REDACTED] Thank you!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: [REDACTED]
Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Monday, February 10, 2020 3:33 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Any updates on this?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Monday, February 10, 2020 10:45 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

I will send a note to CDER [REDACTED] along with Prakash unless others would like to do that. Thank you!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: [REDACTED]
Megan.McSeveney@fda.hhs.gov



From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, February 10, 2020 10:41 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna

<Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi -

(b)(5)

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 10:25 AM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi all - no edits from me

(b)(5)

(b)(5)

(b)(5) I am still catching up on email after a weekend away so apologies if I am being duplicative but, the JIC knows about this request and we will be checking with IMG to make sure the information is up to date (b)(5)

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 9:50 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Attached here. Stacy,

(b)(5)

(b)(5) Any edits are appreciated. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 10, 2020 9:45 AM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Karas, please share with Stacy. Adding her here.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Date: February 9, 2020 at 10:12:58 PM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Thanks, Anna.

If anyone else has edits, please let me know by 10am (or let me know that you need more time).

Megan, (b)(5) Asking in case ASL asks for another update. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 9, 2020 at 9:25:33 PM EST
To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

My laptop is finally working now so I was able to make some edits. (b)(5)
(b)(5) Adding Denise and Michael. (b)(5)

(b)(5)

See attached.

Internal confidential

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Saturday, February 8, 2020 8:13 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: China Inspections Tear Sheet--AMA

Internal, confidential, pre-decisional

Hi Anna and Keagan-

(b)(5)

Once you all review and are in a good place, I can share these with Laura.

Thanks!
Karas

From: Schwartz, Suzanne [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=60FBAC0E12A24633B10181711F7849-SUZANNE.SCH]
Sent: 2/10/2020 11:05:51 PM
To: Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
Subject: RE: Attached - PSCN PPE Market Assessment Report

Thanks Laura.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
Tel: 301-796-6937
Cell: (b)(6)
Suzanne.Schwartz@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Monday, February 10, 2020 9:02 PM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FW: Attached - PSCN PPE Market Assessment Report

Suzanne, et al-

Making sure you saw this report. With some key notes by one of aspr's international team staff.

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov
Desk: 202-260-0666
Cell: (b)(6)

Market Capacity

- In the span of less than 2 weeks, since late January to 5 February 2020, the market's ability to produce personal protective equipment (PPE) to meet demand has been drastically eroded. There is currently an extreme level of demand that has overwhelmed the supply capabilities of the PPE market. However, though the production capacity has been overwhelmed, preliminary assessments have determined that the market collapse is primarily due to aggressive demand. Currently, the specific item in greatest demand is surgical masks. It is anticipated that additional PPE items like gloves, gowns and goggles will experience market pressures.
- The most significant obstacle facing the market today is ensuring surgical masks are sourced and allocated to frontline health workers and other responders in affected countries and those countries most vulnerable to the spread of 2019 nCoV.
- Focusing on surgical masks because of the immediate demand and market pressures, the WHO is estimating that global frontline health emergency responders will require approximately 7% - 10% of the markets' capacity to effectively stop the outbreak.
- The greatest concentration of production for surgical masks is in China. Approximately 50% of the surgical masks capacity is in China. Additional countries include India, Thailand, Malaysia, Japan, Mexico, US, Korea and several European countries.
- Several manufacturers and wholesalers mentioned that production for surgical masks and other PPE items have been significantly shifted to Mexico with Mexico experiencing 100% utilization rates and will for the next 4 to 6 months. Across the market, backlog is running at similar timeframes of 4 to 6 months.
- Finally, any increase in production capacity is estimated to be between 20% and 40% with a ramp-up period of 3 to 4 months.

Logistics

- Overall, the logistical capacity to support transport, storage and distribution of PPE appears to be adequate, but there are some underlying concerns and recent pressures since the beginning of February.
- Public transport is heavily influenced by government restrictions. Logistical providers are expressing substantial concern with any government policies that may negatively impact port operations, air routes and other transport capacities.
- The Chinese government is restricting the export of PPE, and additional governments have also implemented PPE export restrictions or implemented distribution plans to ensure that PPE are available to country-based organizations and facilities. The objective of countries is to ensure that PPE is available for its own citizens, but this has begun to create significant constraints in the market and is expected to decrease the access to and efficient movement globally of PPE supplies if government export restrictions continue.
- In efficient markets, demand and supply are driven by fundamentals such as pricing, quality and efficacy of a product, and consistent needs of the market. However, the market for PPE during the coronavirus is being driven by the political and operational risks, especially surgical masks. This is creating aggressive buying trends and depleting available sources of PPE stock. Consequences include extreme price pressures, long backloads and public misuse of PPE.
- As evident of the consequences of political and operational risks, average demand surges range from 60% to 400% of their historical demand depending on the location and type of product. In some extreme instances, some companies are experiencing 100X of their historical demand. Consequentially, companies are experiencing between 4X and 20X of their historical pricing levels. These price pressures are expected to continue under current conditions.

From: Ryan Morhard <Ryan.Morhard@weforum.org>

Sent: Monday, February 10, 2020 10:29 AM

Cc: GRIFFIN, Michael <griffinm@who.int>; Arnaud Bernaert <Arnaud.Bernaert@weforum.org>

Subject: Attached - PSCN PPE Market Assessment Report

Dear PSCN colleagues,

Please find the market assessment report attached. And thank you to those stakeholders within PSCN who's input has served as a basis for the findings outlined in the report.

Looking forward to our call tomorrow. As a group, I hope we can use that call to consider how, together, we might alleviate some of the pressures and achieve a more optimal response overall.

Thank you again for all. We remain at your disposal.

Ryan

Ryan Morhard
Lead, Global Health Security, International Organizations, and IGWELs
World Economic Forum

Ryan.Morhard@weforum.org

(b)(6)

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/10/2020 11:13:07 PM
To: Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Tarlton, Gail (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3402bd2a372c44268319c10aec4cb827-HHS-Gail.Ta]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]
Subject: FW: ASPR Senior Leadership Brief and HHS International SPOTREP: Novel Coronavirus, Wuhan, China
Attachments: ASPR SLB nCoV 10Feb20 -1700ET.pdf

Attached is the ASPR Senior Leadership Brief and below is information from the HHS International SPOTREP: Novel Coronavirus, Wuhan, China

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HHS International SPOTREP: Novel Coronavirus, Wuhan, China (Update #75)

Source: HHS

What: As of **10Feb20**, **40,533** cases of confirmed 2019-nCoV in **29** locations worldwide.

- **As of 09Feb20, 29,792** air travelers screened. **Eight (8)** persons are under mandatory 14-day quarantine.
- **The Ministry of Health, Labor and Welfare, Japan confirmed 65 additional 2019-nCoV cases among passengers on the Diamond Princess Cruise ship. Testing has been completed for 336 passengers/crews and confirmed 135 2019-nCoV cases in total (23 are AMCITs).**
- **CDC has issued guidance for 2019-nCoV and public travel including cruise ships.**

Global Case Counts

- **Total global confirmed cases = 40,553**
- **Total global confirmed deaths = 910**
- **New Cases (~24 hrs.) = 3,089**
- **International conveyance = 70**
- **Countries with cases = 29**
- **1 U.S. citizen in Wuhan, China, has died due to 2019-nCoV (07Feb20)**

HHS Posture

- **HHS SOC is activated to Level 1 (24/7) as of 02Feb20.**
- **CDC EOC remains activated (Agency Wide).**
- **HHS IMT personnel deployed to repatriation sites across U.S.**

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs

FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



U.S. FOOD & DRUG
ADMINISTRATION

From: Scherf, Uwe [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AED078AAFEC7-UXS]
Sent: 2/11/2020 11:47:04 AM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; CDER-ER-OPS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4aa67416e2b4b80b0ea03681b334525-CDER-ER-OPS]; Choe, Lena [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87ea73b7c30d4023b19ad798cc1c1896-CHOELE]; 2019-nCoV FDA IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b1303ad17cce4c95b45c63ac5c0c31df-2019-nCoV F]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-Ross]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
Subject: RE: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine
Attachments: ASPR News Release 2019-nCoV vaccine1_v7RB for HHS clearance.docxFDA.docx

Megan,

A couple of comments from the diagnostics perspective. Uwe

Uwe Scherf, M.Sc., Ph.D.

Director, Division of Microbiology Devices

OHT7: Office of *In Vitro* Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
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uwe.scherf@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.nct/s/cdrhcustomerservice?ID=1930&S=E>

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 11:14 AM

To: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Choe, Lena <Lena.Cho@fda.hhs.gov>; 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>

Subject: URGENT 1pm deadline for : CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

Importance: High

Hi all – please see the attached PR from ASPR. Asking for concurrent clearance given the short turnaround and the reference to: (b)(5) CDRH -copying Heather Agler through the IMG, as well as Uwe and Kim since this references the EUA. Also, ccing Jennifer Ross from OCET and Toby Lowe (CDRH) given reference to EUA.

Comments are now due today @ 1:00 p.m.

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct: 202-260-6962
Mobile: (b)(6)
Email: naweed.lemar@hhs.gov

From: OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>

Sent: Tuesday, February 11, 2020 9:02 AM

To: OS - ASPA - Clearance <OS.ASPA-Clearance@hhs.gov>; OS - ASPA - Public Health Clearance <OS.ASPA-PublicHealthClearance@hhs.gov>

Cc: Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Walz, Christopher (OS/ASPR/OEA) <Christopher.Walz@hhs.gov>

Subject: CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

Close-Hold

Agency/Office: ASPR

Subject (or headline): 2019-nCoV vaccine development

Materials: Press release

Deadline for comments: Today @ 3:00 p.m.

Planned release date: Wednesday, February 12

Driving Event: Other Transaction Authority agreement expansion signed; company news release timed for stock market opening

V/R,

Naweed Lemar
U.S. Department of Health and Human Services
Direct: 202-260-6962
Mobile: (b)(6)
Email: naweed.lemar@hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/11/2020 12:40:50 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]; Yates, Thomas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=081b97a18deb4148aa33e27729e0cb7c-Thomas.Yate]
Subject: RE: 2 PCCs tomorrow, 11 FEB

Got it – thanks. They will be discussing (b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 12:32 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Yates, Thomas <Thomas.Yates@fda.hhs.gov>
Subject: RE: 2 PCCs tomorrow, 11 FEB

I won't be able to join the 3 pm either – AMA CoV check in (for the time being) overlaps.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 9:29 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Yates, Thomas <Thomas.Yates@fda.hhs.gov>
Subject: RE: 2 PCCs tomorrow, 11 FEB

Dear Anna,

Sounds like Michael and Denise will be attendance. I will ask David to attend for CBER, as I have other meetings scheduled during the PCC. Thanks.

Best Regards,
Peter

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, February 10, 2020 10:55 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Yates, Thomas <Thomas.Yates@fda.hhs.gov>
Subject: 2 PCCs tomorrow, 11 FEB

Hi.

There are two PCCs tomorrow, one from 10:30 AM – 12:00 PM and a second from 3:00 – 4:00 PM.

See description/purpose of meeting below from NSC.

Anna, Peter, or Denise please advise if you plan to attend in person.

Thomas, can we get the SCIF for listening purposes only as per NSC? Thx- m

(b)(5)

Participants are expected to attend in person. With exception of CDC Atlanta and NIAD any SVTC connection will be in listen only mode, though D/A are welcome to have additional participants listen in via SVTC for SA.

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization. FYSA, you will also see an invite for another PCC tomorrow from 1500-1600 in case it is needed as well as an invite for Wednesday morning.

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 2/11/2020 4:08:18 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
Subject: RE: FOR ANNA - EDITS RE: China Inspections Tear Sheet--AMA

Anna has cleared these to move forward. Doing so now. Thank you all!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 3:51 PM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: FOR ANNA - EDITS RE: China Inspections Tear Sheet--AMA
Importance: High

Hi Anna – here are the clean versions of what Karas sent earlier. I do not have any comments. Thank you!

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 1:58 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA
Importance: High

An update (b)(5)

(b)(5)

HHS has asked that I send these back asap, so please let me know if there are any concerns with this approach or any remaining edits. Thank you!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 11:58 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

Caught a typo – otherwise OK here. See attached (b)(5)

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 10:16 AM
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

Thank you!

I've added the edited (b)(5) to the memo. Anna, once you are able to review/sign off, I can move this forward.

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 10:11 AM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

Hi Karas,

Anna is at a meeting and likely won't see this for a little bit.

I think (b)(5) is great. I just have some edits (b)(5)

(b)(5)

Erika

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 10:03 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

Thanks, Mark!

Anna, are you good if I add the below (b)(5) and share the attached version (will remove comments) with ASL?

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 8:13 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

Hi – for OCC, I don't have any legal concerns with the highlighted bullets. thanks

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 6:54 AM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: EDITS RE: China Inspections Tear Sheet--AMA

Morning! Please see edits from Prakash and me - attached are tracked and non-tracked versions.

Mark– wanted to flag that we have highlighted four bullets in this tracked version that have either been added or edited to hopefully help with your review.

While this is still a bit long, [REDACTED] both

Prakash and I are happy to quickly make any edits this morning. Thank you!

Megan McSeveney

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cell: [REDACTED]

Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 6:30 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Thanks, Megan!

Mark, do you need to review for Stacy?

(b)(5)

(b)(5)

Thanks!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 7:59 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi – to follow up on my earlier note – I'll make edits to both these attachments as necessary and will continue to coordinate with Prakash. Thanks and apologies for any confusion! 😊

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cell: (b)(6)

Megan.McSeveney@fda.hhs.gov



From: McSeveney, Megan

Sent: Monday, February 10, 2020 7:43 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi Karas – thank you for your note. I am looking at the attachment and can make those edits there if necessary. If there are other documents we should edit that I may not have or if I can help in any other way please let me know. Also, wanted to thank and share how great it has been working with Prakash, Caitlin, and everyone at OL – the ability to divide and conquer information requests has helped to keep messaging consistent and is greatly appreciated! Best, M

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cell: (b)(6)

Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 7:37 PM

To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Thanks for tracking this down. Can you please make the appropriate edits based on these comments. Thanks!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Sent: Monday, February 10, 2020 7:32 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Adding Mark

From: Rath, Prakash (FDA)

Sent: Monday, February 10, 2020 7:31 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

(b)(5)

(b)(5)

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 3:42 PM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Thank you!

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 3:42 PM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi Karas –

(b)(5)

Thank you!

Megan McSeveney

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cell: (b)(6)

Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 3:33 PM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Any updates on this?

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 10:45 AM

To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

I will send a note to CDER (b)(5) along with Prakash unless others would like to do that. Thank you!

Megan McSeveney

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cel: (b)(6)

Megan.McSeveney@fda.hhs.gov



From: Mair, Michael <Michael.Mair@fda.hhs.gov>

Sent: Monday, February 10, 2020 10:41 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi - (b)(5)

(b)(5)

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Monday, February 10, 2020 10:25 AM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Hi all - no edits from me: (b)(5)

(b)(5)

(b)(5)

I am still catching up on email after a weekend away so apologies if I am being

duplicative but, the JIC knows about this request and we will be checking with IMG to make sure the information is up to date (b)(5)

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Monday, February 10, 2020 9:50 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Attached here. Stacy, (b)(5)

(b)(5) Any edits are appreciated. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 10, 2020 9:45 AM

To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Karas, please share with Stacy. Adding her here.

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Date: February 9, 2020 at 10:12:58 PM EST

To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

Thanks, Anna.

If anyone else has edits, please let me know by 10am (or let me know that you need more time).

Megan (b)(5) Asking in case ASL asks for another update. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Date: February 9, 2020 at 9:25:33 PM EST

To: Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Mair, Michael

<Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: China Inspections Tear Sheet--AMA

My laptop is finally working now so I was able to make some edits.

(b)(5)

(b)(5) Adding Denise and Michael

(b)(5)

(b)(5)

See attached.

Internal confidential

From: Gross, Karas <Karas.Gross@fda.hhs.gov>

Sent: Saturday, February 8, 2020 8:13 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: China Inspections Tear Sheet--AMA

Internal, confidential, pre-decisional

Hi Anna and Keagan-

(b)(5)

Once you all review and are in a good place, I can share these with Laura.

Thanks!

Karas

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/11/2020 8:24:05 PM
To: Kerr, Lawrence (HHS/OS/OGA) [Lawrence.Kerr@hhs.gov]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]
Subject: RE: The Conversation: The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals

Thanks Larry.

Denise

From: Kerr, Lawrence (HHS/OS/OGA) <Lawrence.Kerr@hhs.gov>
Sent: Tuesday, February 11, 2020 6:09 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: The Conversation: The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals

The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals

February 11, 2020 8.53am EST

Authors

1. Christine Crudo Blackburn

Postdoctoral Research Fellow, Scowcroft Institute of International Affairs, Bush School of Government and Public Service, Texas A&M University

2. Andrew Natsios

Director, Scowcroft Institute of International Affairs and Executive Professor, Texas A&M University

3. Gerald W Parker

Associate Dean For Global One Health, College of Veterinary Medicine & Biomedical Sciences; and Director, Pandemic and Biosecurity Policy Program, Scowcroft Institute for International Affairs, Bush School of Government and Public Service, Texas A&M University

4. Leslie Ruyle

Assistant Director Scowcroft Institute of International Affairs, Bush School of Government and Public Service, Texas A&M University

As the new coronavirus, called 2019-nCoV, spreads rapidly around the globe, the international community is scrambling to keep up. Scientists rush to develop a vaccine, policymakers debate the most effective containment methods, and health care systems strain to accommodate the growing number of sick and dying. Though it may sound like a scene from the 2011 movie "Contagion," it is actually an unfolding reality.

In the midst of all of this, a potential crisis simmers in the shadows: The global dependence on China for the production of pharmaceuticals and medical equipment.



Employees work at the center for early phase pharmaceutical development of Asymchem Laboratories Inc, a medical company, on Dec. 4, 2019 in Tianjin, China. Photo by VCG/VCG via Getty Images

Chinese dominance in the pharmaceutical market

We represent an interdisciplinary group of scientists and policymakers at the Scowcroft Institute's Pandemic and Biosecurity Policy Program based at the Bush School of Government at Texas A&M University who have been holding annual summits addressing pandemic-related issues for the past five years. One of our goals is to promote dialogue on potential risks related to pandemics and U.S. security, in this case the disruption of supply chains and availability of medical supplies and drugs.

Today, about 80% of pharmaceuticals sold in the U.S. are produced in China. This number, while concerning, hides an even greater problem: China is the largest and sometimes only global supplier for the active ingredient of some vital medications. The active ingredients for medicines that treat breast cancer and lung cancer and the antibiotic Vancomycin, which is a last resort antibiotic for some types of antimicrobial resistant infections, are made almost exclusively in China. Additionally, China controls such a large market portion of heparin, a blood thinner used in open-heart surgery, kidney dialysis and blood transfusions that the U.S. government was left with no choice but to continue buying from China even after a contamination scandal in 2007.

China is not only the dominant global supplier of pharmaceuticals, but it is also the largest supplier of medical devices in the U.S. These include things like MRI equipment, surgical gowns, and equipment that measures oxygen levels in the blood. Supplies of these essential products have not yet been severely disrupted by the coronavirus, but if China is no longer will or able to supply them to the U.S., thousands of Americans could die.

More concerning still are the limited options available to the U.S. and the rest of the globe to make up the shortfall. It could take years to develop the necessary infrastructure to reestablish U.S. manufacturing capacities and obtain Food and Drug Administration licensure to overcome the loss of the Chinese supply.

When a disease reaches epidemic levels, the first obligation for leaders in any country is to protect their own people. As this current crisis progresses, there may come a point when political leaders in China will face decisions on whether to prohibit the export of pharmaceuticals, medical devices and other vital medical components in order to treat or protect their own people. Such acts would be the logical outcome of an escalating situation. For the 2009 H1N1 pandemic response, for example, the U.S. was pushed to the back of the queue for vaccine deliveries even though we had existing contracts with a major vaccine manufacturer located in another country. Those vaccine deliveries were delayed.



A man wearing a protective face mask sits at a cafe in Beijing on Feb. 9, 2020. A shortage of proactive masks in China is causing many Chinese to stay home. AP Photo/Andy Wong

Disruption of global pharmaceuticals?

While a total loss of active ingredient imports from China might seem far-fetched, we believe the increasing scale of the outbreak moves it closer to the realm of possibility.

About six weeks into international recognition of the epidemic in China, there are already shortages of vital personal protective equipment in both China and the U.S. UPS has transported more than 2 million masks and 11,000 gowns to Wuhan to help alleviate the shortage. But what happens when everyone runs out of protective equipment?

Wuhan is a significant player in the biotechnology and pharmaceutical industry, with multiple pharmaceutical companies located in the city. How many of these factories have closed as a result of the pandemic, and when will those that have closed open back up? Global supply chains could reach a crisis point if they are compromised because Hubei province, where Wuhan is located, is in quarantine and factories are shut down.

Additionally, Wuhan is the location of China's first Biosafety Level (BSL) 4 laboratory, which was opened in 2017 to research SARS and other emerging diseases. It is the only lab in China that can safely handle the world's most dangerous pathogens that pose a significant risk of transmission. Infection, death and quarantine in Wuhan and the surrounding Hubei province is restricting the ability of all types of commerce in the region. Meanwhile, the virus is already creating a significant supply chain imbalance within China. That means those medical supply companies will be under pressure to keep any products produced within the country for protection of their own health care workers, laboratory personnel and the general public.

The regulatory apparatus to insure that the Chinese manufactured pharmaceuticals being exported meet the highest standards of safety and quality control are weak or nonexistent, according to a congressional report last year. The pressure placed on supply chains by the outbreak could further exacerbate existing quality control challenges. In doing so, the virus has highlighted our reliance on China as a U.S. national security issue due to outsourcing our manufacturing capabilities and inability to ensure quality control.

As with all pandemics, the complexity of this outbreak demands international collaboration and transparency. At the same time, U.S. public health officials must acknowledge the country's vulnerability due to our dependence on Chinese production of pharmaceuticals and medical equipment. The U.S. must develop a response plan for the inevitable shortages in the near-term and take necessary actions to reclaim control of our medical supply chain. Continuing to overlook this long-known vulnerability will only lead to catastrophe.

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Sent: 2/11/2020 8:24:12 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: The Conversation: The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals

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Sent: Tuesday, February 11, 2020 6:09 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: The Conversation: The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals

The silent threat of the coronavirus: America's dependence on Chinese pharmaceuticals

February 11, 2020 8.53am EST

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As the new coronavirus, called 2019-nCoV, spreads rapidly around the globe, the international community is scrambling to keep up. Scientists rush to develop a vaccine, policymakers debate the most effective containment methods, and health care systems strain to accommodate the growing number of sick and dying. Though it may sound like a scene from the 2011 movie "Contagion," it is actually an unfolding reality.

In the midst of all of this, a potential crisis simmers in the shadows: The global dependence on China for the production of pharmaceuticals and medical equipment.



Employees work at the center for early phase pharmaceutical development of Asymchem Laboratories Inc, a medical company, on Dec. 4, 2019 in Tianjin, China. Photo by VCG/VCG via Getty Images

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To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHC (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHC (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Odf896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rascio (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffb983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Bone, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6)

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(b)(6) Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acsl-cd]; Bain, Ally P. EOP/OMB (b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D. EOP/NSC
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Bibo, David (b)(6) Driscoll, John J CAPT USCG OSD OUSD POLICY (USA)
(b)(6)

Subject: WCoV (b)(5)
Attachments: Phases of USG nCoV Response_11Feb_Dist.docx; NCoV Control-Containment-Mitigation DRAFT 2.docx
Location: West Wing WHSR JFK ***Please submit WAVES ASAP**
Start: 2/12/2020 8:30:00 AM
End: 2/12/2020 10:00:00 AM
Show Time As: Tentative
Recurrence: (none)

Dear Colleagues,

Thank you for your hard work today. As discussed we will have a (b)(5) from 0830-1000 tomorrow morning and, if necessary, have EEOB Room 445 reserved from 1100-1230 in order to finish the deliverable that is due to the WHTF tomorrow.

Please find attached the CDC paper that was referenced at the afternoon (b)(5). Also, please find attached the updated Phases of USG nCoV Response. As discussed today, finalizing this paper will be the focus of the meeting tomorrow.

(b)(5)

The classification of this meeting will be U//FOUO.

Participants are expected to attend in person, with exception of CDC Atlanta and NIAD . However, D/A are welcome to have additional participants listen in via SVTC for SA.

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization. FYSA, you will also see an invite for another PCC tomorrow from 1100-1230 in case it is needed though you will not need to enter WAVES twice if you are not leaving campus.

Please use the WAVES link to register for attendance. (b)(6)

Best Regards,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/11/2020 9:23:41 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHC (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcedd4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

[kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6); Frater, Eric M (b)(6); Christ, Katelyn E. EOP/NSC (b)(6); Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P. EOP/NSC (b)(6); Rault, Nick M. EOP/NSC (b)(6); Hanna, Cory M. EOP/NSC (b)(6); Burton, Nicholas S. EOP/OMB (b)(6); Garufi, Marc A. EOP/OMB (b)(6); Mroz, Sara K. EOP/NSC (b)(6); Wade, Dave S. EOP/NSC (b)(6); Troye, Olivia EOP/NSC (b)(6); Carlson, Eric J (b)(6); McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J. EOP/NSC (b)(6); Martin, Josh M. EOP/NSC (b)(6); Kanapathy, Ivan J. EOP/NSC (b)(6); Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian J. EOP/NSC (b)(6); Bakewell, Richard A (b)(6); Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J. EOP/NSC (b)(6); Brett Armstrong - D1R [brett.armstrong@gsa.gov]; paul.detitta@gsa.gov; Marwaha, Brianna C (b)(6); Carstens, Virgil W (b)(6); Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D. EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Sugarman, AJ J. EOP/WHO (b)(6); Planning, David M. EOP/WHO (b)(6); Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6); Greene Richard S. (GH/HIDN) [USAID] [rgreene@usaid.gov] [rgreene@usaid.gov]; Baehr, James S. EOP/WHO (b)(6); Magrino, Christopher (b)(6); debbie.w.seguin (b)(6); william.ferrara (b)(6); Tobin, Elizabeth D. EOP/NSC (b)(6); Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J (b)(6); Music, Chris G. EOP/OMB (b)(6); Ali, Nausher (b)(6); Burris, Meghan K. EOP/WHO (b)(6); Henning, Alexa A. EOP/WHO (b)(6); Daravi, Roma S. EOP/WHO (b)(6); Horstman, John H. EOP/WHO (b)(6); MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA) (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Martin, Michael E. EOP/NSC (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC (b)(6); Gray, Alexander B. EOP/NSC (b)(6); Rubini, Jeffrey H. EOP/NSC (b)(6); Stahlman, James E CIV OSD OUSD POLICY (USA) (b)(6); Ulliyot, John L. EOP/NSC (b)(6); Stufft, Julie M. EOP/NSC (b)(6); Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC (b)(6); Davis, May M. EOP/WHO (b)(6); Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B. EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6); Thallam, Satya P. EOP/OMB (b)(6); Allen, Ronald G. EOP/NSC (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB (b)(6); Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D. EOP/NSC (b)(6); Mesquita, Mario M (b)(6); Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA) (b)(6); DL Chief of Staff Office (b)(6); Ash, Deborah J. EOP/NSC (b)(6)

(b)(6) Reilly, Tom M. EOP/OMB (b)(6) Havranek, John
(b)(6) Dumm, Christopher M (b)(6) FORET, VERNON T
(b)(6) Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew
(ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC (b)(6) JACKSTA,
LINDA L (b)(6) Parra, Yolanda A (b)(6) Carter, Hillary H. EOP/NSC
(b)(6) Galkowski, James J. EOP/WHO (b)(6) Tokumasu de
Silva, Miriam E (b)(6) Doyle, Emma K. EOP/WHO (b)(6) Lason, Adam
J. EOP/NSC (b)(6) McPheeME (b)(6) Carson, Tracy L (Geneva) (b)(6)
Bibo, David (b)(6) Driscoll, John J CAPT USCG OSD OUSD POLICY (USA)
(b)(6)

Subject: WCoV (b)(5)
Attachments: Phases of USG nCoV Response_11Feb_Dist.docx; NCoV Control-Containment-Mitigation DRAFT 2.docx
Location: West Wing WHSR JFK ***Please submit WAVES ASAP**

Start: 2/12/2020 8:30:00 AM
End: 2/12/2020 10:00:00 AM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

Thank you for your hard work today. As discussed we will have (b)(5) from 0830-1000 tomorrow morning and, if necessary, have EEOB Room 445 reserved from 1100-1230 in order to finish the deliverable that is due to the WHTF tomorrow.

Please find attached the CDC paper that was referenced at the afternoon (b)(5). Also, please find attached the updated Phases of USG nCoV Response. As discussed today, finalizing this paper will be the focus of the meeting tomorrow.

(b)(5)

The classification of this meeting will be U//FOUO.

Participants are expected to attend in person, with exception of CDC Atlanta and NIAD . However, D/A are welcome to have additional participants listen in via SVTC for SA. Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization. FYSA, you will also see an invite for another PCC tomorrow from 1100-1230 in case it is needed though you will not need to enter WAVES twice if you are not leaving campus.

Please use the WAVES link to register for attendance. (b)(6)

Best Regards,

Phil

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/12/2020 9:10:16 AM
To: [REDACTED] (b)(6)
Subject: Fwd: RADM Hinton - Draft corona QAs supply chain2_11_20.docx
Attachments: Draft corona QAs supply chain2_11_20.docx

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Date: February 11, 2020 at 10:44:10 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RADM Hinton - Draft corona QAs supply chain2_11_20.docx

Hi Denise,

Attached are the TP's and QA for tomorrow's briefings. [REDACTED] (b)(5) as these are likely the topics to come up, if any. The IMG is looking at this now, and we'll talk through any last minute edits when we meet with you in the morning (HHS, 10:15).

Thank you,
Prakash

Food and Drug Administration
Office of Legislation
301-796-0026
Prakash.Rath@fda.hhs.gov

From: Patel, Paras M [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4F5E608BC5F24805A25560BE083E1FC8-PATELP]
Sent: 2/12/2020 9:45:31 AM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jackson, LeeAnne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=736277c6fd7b486db5807177dc64a362-LJACKSO1]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]; Hornung, Matthew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab78f29c3a884a86bd5ba9e45124d704-Matthew.Hor]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Simms, Joshua [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b4d1b8521364ce2b0dccc89b861b673-JOS]; Zablan Jr., Russell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=214878514387409eaa619c1e0b2b6886-RZABLAN]; Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eaec1867d40a3b39c4031cb35490f-LJS]; Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Marders, Julia A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dbfe501809ec40bbb5d638295b7a3cf9-JBM]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Hashemi, Sema [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e1d21c497e845739552ff0a9c6c9bb1-SHashemi]; Gabrel, Celia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41f5014f53bf40fcbad401e5ebfb4a1a-GABRELC]; Christensen, Lane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]; Sutton, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9a9c5c5c9a1410dbc58c6611b0d1864-WXS]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Rotstein, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a3b17ebfcf14a6cb8e94f322906badd-DRotstei]; Glover, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23fc3452dfd0414184cbb290047b7865-Mark.Glover]; Ngan, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7a30838c8bc49428cbe4959ae8ed6c-NGANK]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Ellis, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dec0284840704f568a8b9f314058ad63-Patricia.El]; Block, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5211fe9c85343da86415679e4afbbda-Frank.Block]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; 2019-nCoV FDA IMG Operations [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ab16f553eb6f469c9cad541559a5ceb3-2019-nCoV F]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
CC: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]
Subject: RE: Urgent: Information request for ASPR White House Briefing

Morning,

Please review DSS bullets for WH request below. The following bullets can be provided for CDER FDA DSS for the“quantitative or qualitative” request.

- **FDA/CDER Drug Shortage Staff (DSS) has an established reporting process for medical drug product shortages. Manufacturers are required to report potential drug shortages to the FDA, and are required to report the reasons for shortages and the expected duration of shortages on the FDA website. Title X of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, signed on July 9th, lists the mandatory reporting requirements for manufacturers. Please refer to: <https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages>**
- **CDER/DSS has established direct communications and provided a direct point of contact at DSS for manufacturers of human medical drug products regarding impacts to API and/or finished drug product from the COVID-19 event. Regulatory representatives for approved medical drug products for the US market have been contacted and directly requested to provide supply chain status for their human medical drug products supply affected by facilities that could be impacted by the COVID-19 event in China. In particular, API and/or finished dosage forms, current or future production of API and/or finished drug products and any projected impact to drug product supply for the US market.**
- **CDER/DSS participates in a monthly Global Regulatory Shortage working group meeting of regulators at EMA (European Medicines Agency), MHRA (Medicines & Healthcare products Regulatory Agency: UK), TGA (Therapeutic Goods Administration: Australia), and Health Canada. Respective regulatory authorities are also monitoring impact of COVID-19 to drug product supply.**

Thank You...

Paras M. Patel, RPh, MBA
CAPT, U.S. Public Health Service
Senior Regulatory Review Officer
CDER Drug Shortage Staff/ Office of the Center Director
Food and Drug Administration
(301)-796-8465

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 6:54 AM

To: Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Hornung, Matthew <Matthew.Hornung@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hashemi, Sema <Sema.Hashemi@fda.hhs.gov>; Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; Sutton, William <William.Sutton@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Block, Frank <Frank.Block@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>

Subject: Urgent: Information request for ASPR White House Briefing

Importance: High

Good morning,

I realize many of you have already received the attached request from HHS/ASPR to review and add (b)(5) (b)(5) for a White House briefing on Friday (this is the same request we mentioned during yesterday afternoon's IMG and AEG meetings). In addition to FDA, other HHS partners (CDC, BARDA, SNS, and ASPR/Division of Critical Infrastructure Protection (CIP)) have been asked to contribute (b)(5) information.

The deadline for FDA to return edits to ASPR is 2:00 pm today. Ideally, we'd like to send a single FDA response back to ASPR, so if you could send me your edits/comments by **12:00 today** that would be super so we can give leadership the opportunity to review before 2:00 if needed since this issue is a very high priority. CDRH, we've seen your great comments about (b)(5) and will work to incorporate those as well.

If you have any questions or concerns, just let Michael or me know.

Many thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) (b)(6) (cell)
brooke.courtney@fda.hhs.gov

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/12/2020 11:38:17 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Leggin, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; Strachman-Miller, Jason [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5338a90c67824a729f5c0f630449a56c-Jason.Strac]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: SG Testimony at Roundtable
Attachments: Gottlieb-Senate-Statement-Homeland-Security-Governmental-Affairs-1.pdf

FYI

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 11:34 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Anderson, Erika (CFSAN, ISS) <Erika.Anderson1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Subject: SG Testimony at Roundtable

Testimony

Are We Prepared? Protecting the U.S. from Global Pandemics: Statement before the Senate Committee on Homeland Security and Governmental Affairs

HEALTH CARE

February 12, 2020

The epidemic spread of coronavirus in China — along with community transmission in Singapore, Hong Kong, and Japan — sharply increase the chance that we endure pandemic spread. Worse still, the novel coronavirus may become endemic. It could take a new position as a more sinister member of the seasonal pathogens that circulate each year and infect humans.

The next month is critical. We must prepare for the prospect that the virus evaded our border protections and was already introduced into the U.S. in late December or early January — when it first appears to have become epidemic in

China's Hubei province. Those index cases could have seeded community spread, and eventually, outbreaks could emerge in America. We have the capacity to contain small outbreaks. But we need to be vigilant and ready.

Models suggest that from the time of first introduction of the virus into China – which we now suspect occurred sometime in November – to the time of epidemic spread in China, was about 10 weeks.^[i] The experience in the U.S. is likely to be different, not least because our awareness of this risk is prompting collective action that can limit spread. But China's experience shows that if cases were imported into the U.S. in early January and remain undetected, then we could still be early in our own evolution toward broader outbreaks. Right now, we're depending largely on clinical surveillance as our primary tool for identifying potential outbreaks since we're just now deploying diagnostic tools to the Laboratory Response Network. Moreover, we still haven't broadened our screening criteria to include patients who don't have a connection to recent travel to China. This limits our ability to identify secondary spread. So, we may know we're experiencing outbreaks of this disease only when a cluster of cases of atypical pneumonia present to a hospital and trigger closer scrutiny by health officials. By that time, there could be dozens or even hundreds of cases in a local community. Controlling broader spread could become a challenge.

Full Testimony

I want to focus my observations on the vulnerability of our supply chain for drugs and medical devices. Some shortages or near shortages may be inevitable in U.S. as a result of crisis in China. Our drug and medical device supply chain is pointedly and precariously dependent on production in China for our finished goods. In many cases it isn't the finished drugs or medical devices that are being manufactured largely or exclusively in China. Nor is it the intermediate products like the active pharmaceutical ingredients (API). It is lower margin, low technology starting materials and components that – over time – have become sole sourced in China.

Securing alternative supply in the setting of a crisis takes time. But here are steps U.S. regulators can take in the near term, working with Congress and other partners, to lessen the potential impact of supply disruptions on Americans by identifying vulnerabilities and bringing substitute supply online. There are also longer-term policy steps that we could take to reduce the vulnerabilities created by these choke points in the supply of critical public health goods.

I want to address in greater detail these issues as they relate to drugs and production in China. About 40 percent of generic drugs sold in the U.S. have only a single manufacturer. A significant supply chain disruption could cause shortages for some of many of these products.ⁱⁱ

Last year, manufacturing of intermediate or finished goods in China, as well as pharmaceutical source material, accounted for 95 percent of U.S. imports of ibuprofen, 91 percent of U.S. imports of hydrocortisone, 70 percent of U.S. imports of acetaminophen, 40 to 45 percent of U.S. imports of penicillin, and 40 percent of U.S. imports of heparin, according to the Commerce Department. In total, 80 percent of the U.S. supply of antibiotics are made in China.ⁱⁱⁱ

While much of the fill finishing work (the actual formulation of finished drug capsules and tablets)

is done outside China (and often in India) the starting and intermediate chemicals are often sourced in China. Moreover, the U.S. generic drug industry can no longer produce certain critical medicines such as penicillin and doxycycline without these chemical components.^{iv}

According to a report from the US-China Economic and Security Review Commission, China's chemical industry, which accounts for 40 percent of global chemical industry revenue, provides a large number of ingredients for drug products.^v It's these source materials --- where in many cases China is the exclusive source of the chemical ingredients used for the manufacture of a drug product -- that create choke points in the global supply chain for critical medicines.

Moreover, when it comes to starting material for the manufacture of pharmaceutical ingredients, a lot of this production is centered in China's Hubei Province, the epicenter of coronavirus. Most drug makers have a one to three-months of inventory of drug ingredients on hand. But these supplies are already being drawn down. Among big API makers in Wuhan are Wuhan Shiji Pharmaceutical, Chemwerth, Hubei Biocause, Wuhan Calmland Pharmaceuticals.^{vii}

There are steps that we can take -- both in the short term as well as the long run -- to expand our supply chain for making these raw and intermediate components of drug production and mitigate risks to our supply chain. In the setting of the current public health crisis related to the novel coronavirus, I want to focus my remarks today on some of these potential actions.

We're facing the potential for unprecedented supply chain disruptions. You can't easily switch component part suppliers -- either starting material for the manufacture of drugs or components for device devices. You have to qualify those alternative sources, make sure they meet regulatory standards for Good Manufacturing Practices (GMPs), and meet the conditions set by those incorporating these materials into their finished goods. Even if FDA is able to offer manufacturers flexibility in making these component changes, substitutions are often complex.

Right now, we may not even be aware of the full scope of these vulnerabilities. In many cases, we don't have established systems for tracking down to the level of these components, to easily identify the choke points. This is true even when it comes to where API is sourced. We rely on our ability to track the finished products. This isn't just a coronavirus challenge. An earthquake or political unrest in a major manufacturing region could present the same problems. How can we take steps to try and address some of these significant challenges?

First, we can work to bring on alternate supply. After Hurricane Maria devastated Puerto Rico, and took offline fully 10 percent of the manufacturing capacity for drugs intended for the U.S. market, the FDA took proactive steps to restart facilities that manufactured key products, and identify alternative suppliers for some products where significant and potentially harmful disruptions were believed to be unavoidable owing to the damage.^{viii} There's idle manufacturing capacity that can be developed to address some of the immediate needs. India, for example, has about 1,500 plants that manufacture APIs and are running at 40 percent capacity.^{ix}

Second, we also need a better system for identifying these supply chain choke points. When it comes to the kinds of starting materials that may have been disrupted by the crisis in China, FDA would be dependent on manufacturers to identify these supply choke points. This is challenged by the current shortage framework. It relies on a passive reporting system from manufacturers, where we might find out too late of impending shortage. It may not work in a crisis situation like this where information and reporting are imperfect.

In the near term, FDA can issue a solicitation for such information. U.S. officials should already have some awareness of the key components that are manufactured in China, and in the Hubei Province particular. But in the longer term, we need a more systematic process for collecting this

information. This is where Congress can help, by giving the FDA authority to look not only at the supply of finished products but to also identify circumstances where key components may have only a single source across an entire category of products. This may take the form of a requirement that manufacturers develop risk management plans that explicitly surface critical supply chain choke points. In turn, we could require companies to take steps to identify alternative sources in the event of a major disruption. It isn't just supply disruptions we need to be fearful of. In the setting of a public health crisis in a country that hosts the manufacture of critical components, a government may seek to withhold supply or even nationalize key facilities if the components are essential to their own relief efforts. A nation could seek to satisfy its in country needs before they ship outside their borders. Such a circumstance arose with respect to the manufacture of flu vaccine after the H1N1 pandemic.x

Standing up new sources of supply is not as complex as creating new facilities for manufacturing intermediate and final drug products. That's because these starting components and ingredients fall under the GMP requirements of the finished manufacturer's supplier controls. This means that the ingredients and parts are not independently subject to GMP requirements if they're not themselves the drug product or finished device. So, this flexibility can make it easier to more quickly establish alternative manufacturing sites for the production of source material and other inputs. It doesn't require that these new facilities undergo all of the more time consuming GMP requirements as the finished drug. Only finished products need to meet these standards. It's clear now that we are also going to have significant delays in FDA inspections of facilities in China, and maybe in other foreign locations. This could make efforts to identify new manufacturing sites more challenging if those facilities are required to be inspected by the agency. The falloff in inspectional capabilities could also create some immediate consumer risks.

There are steps we can take to offset these challenges. For example, Congress can support efforts by FDA to increase import sampling and testing of regulated goods coming from China, since the agency will be hard pressed to make up for the lost inspectional activity, even after the current crisis has subsided. This will require additional resources for FDA's inspectional program. The FDA could also consider revising its risk-based inspection model and plan for 2020. Based on the shutdown in Chinese manufacturing and the need for alternate supplies, the agency might need to redefine the highest risk facilities and shift some of the focus of its inspection resources once facilities are brought back online. These efforts can be supported by Congress. The FDA's inspectional activities and its field force are on the front lines of the agency's historic consumer protection mission. The agency has the expertise to adapt to these challenges, but it can benefit from focused resources and authorities that support these efforts in both the near and long term. It's not just generic drugs that could fall into shortage. Brand drugs use contract research organizations like WuXi in China for development work, and global clinical trials enroll patients China.xi There are 16,490 studies registered on Clinicaltrials.gov in China and 5,086 studies are currently recruiting. This is about 10 percent of all of the actively recruiting studies. The clinical trial work, as well as the work conducted by China CROs has -- in many cases -- has stopped.xii

As a consequence, some new drug programs could be delayed as innovators are forced to change clinical trial enrollment plans, amend protocols, or shift certain critical development activities to other CROs located in other regions. This could delay regulatory filings on new drugs. We also must address potential device shortages. Medical devices operate under different framework than drugs. It may be harder to identify and mitigate potential shortages. We should adopt the same practices we've implemented for drugs -- which requires manufactures to give FDA early notification of potential shortage situations. More than a year ago, FDA first put forward such a proposal. That proposal was incorporated into the President's current budget. Finally, we should also contemplate for medical devices a similar framework to the one I believe we need for drugs. It would require manufacturers to report to FDA when there is a key component that is sole sourced and where alternate supply cannot be easily obtained.

While we hope no shortages will result from the tragic epidemic, given the concentration of production work in Wuhan, the risk is real. Those risks can be reduced through careful planning. In the long run, there are structural changes we can make to reduce these risks for when next global crisis arises. It starts with shifting our emphasis. We've been focused on the risk that finished goods can fall into shortage owing to a supply disruption. In a world where the manufacture of components and source material has become highly centralized around a small number of regions and facilities, we need to pay equal attention to identifying these other choke points and taking steps to make sure that critical production doesn't hinge on a single location.

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/12/2020 3:20:14 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: supply chain/coronavirus

Yes - CDRH held a call with CDC Monday to discuss (b)(5)

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 3:15 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: supply chain/coronavirus

(b)(5)

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 3:07 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: supply chain/coronavirus

Just FYI – getting news coverage – Chinese researchers report that the median incubation period for 2019-nCoV is 3.0 days (range, 0 to 24.0 days).

<https://www.medrxiv.org/content/10.1101/2020.02.06.20020974v1>

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 3:04 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: supply chain/coronavirus

Plus Michael and Erika – I just dialed into AMA update call and need to know if there is anything urgent that came up in the past 24 hours I need to flag for the Secretary. I expect the item below will come up. Thank you in advance.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 2:54 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: supply chain/coronavirus

We need an answer here to the questions the Hill is raising. Can IMG get back to us?

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Wednesday, February 12, 2020 2:38 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>
Subject: Fwd: supply chain/coronavirus

Begin forwarded message:

From: "McMillin, Virginia D. EOP/WHO" <(b)(6)>
Date: February 12, 2020 at 2:20:37 PM EST
To: "Pence, Laura (HHS/ASL)" <Laura.Pence@hhs.gov>
Cc: "Gross, Karas (FDA/OC)" <Karas.Gross@fda.hhs.gov>, "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>
Subject: RE: supply chain/coronavirus

Many thanks!

Virginia Heppner McMillin
Special Assistant to the President
Office of Legislative Affairs
(b)(6)

From: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>
Sent: Wednesday, February 12, 2020 1:46 PM
To: McMillin, Virginia D. EOP/WHO <Virginia.D.McMillin@who.eop.gov>
Cc: Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>
Subject: RE: supply chain/coronavirus

We've discussed and are on top of it. Thanks!

From: McMillin, Virginia D. EOP/WHO <(b)(6)>
Sent: Wednesday, February 12, 2020 1:44 PM
Cc: Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Gross, Karas (FDA/OC) <Karas.Gross@fda.hhs.gov>
Subject: Re: supply chain/coronavirus

Jen off. She called me about this and I agree with her- I think we need a better answer than the one that was given today at the briefing moving forward. It did not provide the details members wanted and did not go over well.

Virginia McMillin
Special Assistant to the President
Office of Legislative Affairs
(b)(6)

On Feb 12, 2020, at 1:42 PM, Kuskowski, Jennifer (McConnell) <(b)(6)> wrote:

Hey there – can you provide details on how HHS and specifically FDA are responding to concerns about the potential for

(b)(5)

Appreciate any and all information you can share on this issue. I'd anticipate it coming up at Azar's budget hearing tomorrow, and perhaps in other venues as members continue to discuss the ramifications of the Coronavirus.

Thanks!

Jen

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/12/2020 10:22:42 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbec5f5eeb7f3d-Heather.Jan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]
Subject: For your review: draft statement on outbreak response
Attachments: Draft Statement.docx
Importance: High

I am sharing this first take at a statement outlining our response efforts to make sure it strikes the right tone as well as captures the topics of importance. If you think we are on the right path, please send me any initial comments and I will take it through the IMG. I'll send you a final draft before it goes to the Commissioner and then HHS. Thank you.

From: Gross, Karas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B415D86EC634C536453B6-KARA.GROSS]
Sent: 2/12/2020 11:11:38 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]
Subject: RE: For your review: draft statement on outbreak response
Attachments: Draft Statement.docx

Some initial thoughts here and in the document. Will review more as it moves forward.

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 10:23 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: For your review: draft statement on outbreak response
Importance: High

I am sharing this first take at a statement outlining our response efforts to make sure it strikes the right tone as well as captures the topics of importance. If you think we are on the right path, please send me any initial comments and I will take it through the IMG. I'll send you a final draft before it goes to the Commissioner and then HHS. Thank you.

From: Jones, Estella [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99A7F2BD273D42E18320F0667688B0C1-ESTELLA.JON]
Sent: 2/12/2020 11:20:49 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: Support to combat 2019-nCoV

I sent it to Fisher, Mair, Sadove and Tracy (who was out with hand surgery). They said there was no more OCET money. I can check with Daniela to see if she socialized it in CDER (hard to imagine she wouldn't).

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 10:52 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: RE: Support to combat 2019-nCoV

(b)(5)

From: Jones, Estella <Estella.Jones@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 10:03 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FYI: Support to combat 2019-nCoV
Importance: High

I worked with Daniela when I was CBER years ago. Daniela (prior CBER but now CDER) is seeking funding for CoV work and OCET said no funds. Is that still true? (b)(5) No one in the world can image a mouse the way they can. I would think this would be a therapeutic therapy but it was shot down at the gate at the end of January.

What do you think? <https://www.niaid.nih.gov/about/irf-aerobiology-core>

No one ever asked Daniela how much funding she was seeking.

From: Verthelyi, Daniela I <Daniela.Verthelyi@fda.hhs.gov>
Sent: Tuesday, January 28, 2020 1:21 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: RE: Support to combat 2019-nCoV

Thanks Estella, we will.

Best,

Daniela

From: Jones, Estella <Estella.Jones@fda.hhs.gov>
Sent: Monday, January 27, 2020 6:21 PM
To: Verthelyi, Daniela I <Daniela.Verthelyi@fda.hhs.gov>
Subject: RE: Support to combat 2019-nCoV

Hi Daniela,

We think that this outbreak will get more attention and possibly funding in the future but right now we don't have funds to address it. I will keep you posted on any new developments: (b)(5)

(b)(5) Tracy is out of the office right now but I will make sure that she is aware.

Best,

Estella

From: Verthelyi, Daniela I <Daniela.Verthelyi@fda.hhs.gov>
Sent: Monday, January 27, 2020 4:41 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: Support to combat 2019-nCoV

Dear Estella,

I would like your take on the current Corona virus crisis. As you know, a new betacoronavirus, 2019-nCoV, has emerged discovered in Wuhan, Hubei province of China and it appears to spread from human to human through aerosols. The virus has so far infected at least 2,800 people in China and killed at least 82. Chinese officials are reporting sustained person-to-person spread is occurring in China. World Health Organization is closely monitoring the situation as China has quarantined 41 million people in 13 cities to contain the disease. As of January 27th 2020, 16 countries including United States (5 cases) have confirmed 2019-nCoV cases. Taking the current scenario into consideration, I believe we can expect a rapid surge in vaccines and therapeutics aimed at controlling the new pathogen. I wanted to know your thoughts on immediately committing resources to develop animal models the lab to help with the development and regulation of the therapeutics and vaccines that will come to the Agency. Our lab has recently developed mouse models for emerging and re-emerging infectious diseases including Zika and Ebola virus and are currently characterizing our new mouse model for Dengue virus: (b)(5)

(b)(5)

Please let us know, if these align with the priorities of the Office of Counter terrorism and Emerging Threats and if funding might be available to support these projects. Please don't hesitate to contact us if you think we can help with anything to combat this new public health crisis.

Thanks,

Daniela Verthelyi

From: Ernest Smiley (b)(6)
Sent: 2/13/2020 6:37:29 AM
To: Stacey.A.Dixon (b)(6); Alexander.Berger (b)(6); Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FDA and NGA Collaboration

Dr. Dixon,

We appreciate your leadership and support.

Thanks

ERNEST L. SMILEY, MS, MBA, CISM, CGEIT, CRISC, CPM
CHIEF DATA SCIENTIST
KINGDOM CAPITAL

(b)(6)

www.KingdomCapital.com

-----Original Message-----

From: Stacey.A.Dixon (b)(6)
Sent: Wednesday, February 12, 2020 9:50 AM
To: Ernest Smiley (b)(6); Alexander.Berger (b)(6); Denise.Hinton@fda.hhs.gov
Cc: DDStaff (b)(6)
Subject: RE: FDA and NGA Collaboration

Classification: UNCLASSIFIED
=====

Ernest,
Thank you for the forward.

Admiral Hinton, Alex Berger is our agencies point person for coronavirus. He will connect you with the team in our agency that is working this issue.

Sincerely,
Stacey

-----Original Message-----

From: Ernest Smiley (b)(6)
Sent: Monday, February 10, 2020 8:46 PM
To: Dixon Stacey A NGA-DD USA CIV (b)(6)
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: [Non-DoD Source] FDA and NGA Collaboration

Dr. Dixon,

Please forward NGA's point of contact for Admiral Hinton.

Admiral Hinton is the Chief Scientist for FDA and needs to collaborate with NGA for the coronavirus.

Admiral Hinton is currently collaborating across DoD and other federal and commercial organizations.

Thanks for your leadership and dedication

ERNEST L. SMILEY, MS, MBA, CISM, CGEIT, CRISC, CPM

CHIEF DATA SCIENTIST

Kingdom Capital

(b)(6)

www.KingdomCapital.com <<https://protect2.fireeye.com/v1/url?k=11a8721a-4db1f30f-11a85843-0cc47a31ba6c-e5533218a595de8e&q=1&e=f0b0ba5f-6dac-4834-9aca-cff7ffbbd739&u=http%3A%2F%2Fwww.kingdomcapital.com%2F>>

=====
Classification: UNCLASSIFIED

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/13/2020 2:17:12 PM
To: McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeeee5ffeeb7f3d-Heather.Jan]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Barber, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a326d10d4c5483f843dbb9d59bf1e5d-Daniel.Barb]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: For Clearance CDER FAQs and Inside FDA for employees

All

Below please find the below internal and external docs for your clearance. They have cleared the IMG, including OCC.

Please let me know if there are edits ASAP today.

Thank you very much.

Laura

1. **EXTERNAL [fda.gov](#) - CDER FAQs page** (latest below – CDER wants to post this week). Added—with CDRH and CBER clearance—additions on how to report biologic and device shortages included in highlight below. We may also want to consider adding the product shortages contacts and a brief statement on our role around shortages to the [fda.gov](#) landing page, where this new CDER page will be linked (What’s new, etc.).

2. **INTERNAL – New InsideFDA FAQs page for FDA employees, from Occupational Health** (latest below – ready to post today, if cleared – these are based on actual questions we are receiving from employees, mostly based on CDC website and FDA travel info, which is already posted)

DRAFT CDER FAQs page ([fda.gov](#))

(b)(5)

(b)(5)

Draft InsideFDA FAQs for FDA employees, from Occupational Health

(b)(5)

(b)(5)

(b)(5)

From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/13/2020 2:55:30 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: Urgent: Information request for ASPR White House Briefing
Attachments: nCOV Supply Chain WH briefing data call 02112020_FDAedits021320.pptx

Hi all – (b)(5)
(b)(5)
(b)(5) Thank you!

Megan McSeveney
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 13, 2020 2:54 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Let's run concurrent OCC review give the turn around time on this.

Courtney, I will look at this shortly, but you (OCET) should close the loop with ASPR. Just make sure Keagan and I have the finals.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Thursday, February 13, 2020 2:13 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Importance: High

Anna and Keagan,

Attached is the draft FDA content for ASPR for tomorrow's White House briefing. (b)(5)

(b)(5)

(b)(5)

After your review, just let me know if you'd like to send the slides back to ASPR or if you'd like me to.

I'm also separately attaching (b)(5)

(b)(5)

Thanks,
Brooke

From: Courtney, Brooke

Sent: Thursday, February 13, 2020 1:37 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Yes, I will send them shortly—I'm in the process of adding the additional information requested below. OCC still needs to review the new information, which I've already sent to them.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, February 13, 2020 1:33 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Can I see the slides please?

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Thursday, February 13, 2020 12:53 PM

To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

I haven't heard anything further from the ASPR team so let's just proceed based on what we know and loop back with them.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Thursday, February 13, 2020 10:52 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Hi Anna,

Thank you for the input. (b)(5)

(b)(5)

Thanks,
Brooke

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Thursday, February 13, 2020 10:47 AM

To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Plus Keagan

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Thursday, February 13, 2020 8:42 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Subject: FW: Urgent: Information request for ASPR White House Briefing

Importance: High

Hi Anna and Denise,

For your review this morning, attached are the combined FDA comments/edits on (b)(5) for tomorrow's White House meeting. The attached slide deck includes input from (b)(5) (b)(5) (b)(5) OCC reviewed the content last night (b)(5) (b)(5)

Also, while it's possible FDA could go more in detail with ASPR and CDC during a meeting if needed, (b)(5)

(b)(5)

We'd like to return these to ASPR this morning if at all possible.

Thanks!
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) / (b)(6) (cell)
brooke.courtney@fda.hhs.gov

From: Courtney, Brooke

Sent: Wednesday, February 12, 2020 6:54 AM

To: Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Brad Leissa (brad.leissa@fda.hhs.gov) <brad.leissa@fda.hhs.gov>; Roberts, Rosemary (Rosemary.Roberts@fda.hhs.gov) <Rosemary.Roberts@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Hornung, Matthew <Matthew.Hornung@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hashemi, Sema <Sema.Hashemi@fda.hhs.gov>; Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; 'Sutton, William' <William.Sutton@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Ngan, Kelly (Kelly.Ngan@fda.hhs.gov) <KELLY.NGAN@FDA.HHS.GOV>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Block, Frank <Frank.Block@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>

Subject: Urgent: Information request for ASPR White House Briefing

Importance: High

Good morning,

I realize many of you have already received the attached request from HHS/ASPR to review and add (b)(5) (b)(5) for a White House briefing on Friday (this is the same request we mentioned during yesterday afternoon's IMG and AEG meetings). In addition to FDA, other HHS partners (CDC, BARDA, SNS, and ASPR/Division of Critical Infrastructure Protection (CIP)) have been asked to contribute (b)(5) information.

The deadline for FDA to return edits to ASPR is 2:00 pm today. Ideally, we'd like to send a single FDA response back to ASPR, so if you could send me your edits/comments by **12:00 today** that would be super so we can give leadership the opportunity to review before 2:00 if needed since this issue is a very high priority. CDRH, we've seen your great comments about (b)(5) and will work to incorporate those as well.

If you have any questions or concerns, just let Michael or me know.

Many thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) (b)(6) (cell)
brooke.courtney@fda.hhs.gov

From: Black, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AAF8A19F3672492293A7C1B2D1498059-JENNIFER.BL]
Sent: 2/13/2020 4:04:33 PM
To: Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Aguilar, Paul [Paul.Aguilar@fda.hhs.gov]; Pennington, Caitlin [Caitlin.Pennington@fda.hhs.gov]; Schipper, Jodi [jodi.schipper@fda.hhs.gov]; McSeveney, Megan [Megan.McSeveney@fda.hhs.gov]; Howard, Megan [Megan.Howard@fda.hhs.gov]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shirley, Mayo [Mayo.Shirley@fda.hhs.gov]; Rath, Prakash (FDA) [Prakash.Rath@fda.hhs.gov]
CC: Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]
Subject: Prep for Friday Congressional Phone Briefing on Supply Chain
Attachments: Draft Statement AA.docx021320_CDRHCDERCFSANORA1515AA (003).docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA .docx
Location: RADM Hinton's office or WebEx
Start: 2/13/2020 4:15:00 PM
End: 2/13/2020 4:45:00 PM
Show Time As: Busy

Required Attendees: Black, Jennifer; Abram, Anna; Gross, Karas; Tantillo, Andrew; Aguilar, Paul; Pennington, Caitlin; Schipper, Jodi; McSeveney, Megan; Howard, Megan; Hinton, Denise; Shirley, Mayo; Rath, Prakash (FDA)

We will use this time to prep for the Friday (1/14) briefings on supply chain during the coronavirus outbreak. Questions that we will prepare for will be based on what was asked during the calls and briefings over the last two days.

FDA and ASPR will have two briefings tomorrow and a prep in the morning. They will be similar to the ones today where we provide opening remarks and answer QA. We can come prep with you at 4:15 today.

Attachments:

Dr. Hahn Statement as of 2/13 3:55pm
Opening talking points from briefing call today
Full Talking Points Document

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From: Black, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AAF8A19F3672492293A7C1B2D1498059-JENNIFER.BL]
Sent: 2/13/2020 4:04:33 PM
To: Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Howard, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: Prep for Friday Congressional Phone Briefing on Supply Chain
Attachments: Draft Statement AA.docx021320_CDRHCDCERCFSANORA1515AA (003).docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA .docx
Location: RADM Hinton's office or WebEx
Start: 2/13/2020 4:15:00 PM
End: 2/13/2020 4:45:00 PM
Show Time As: Busy

Required Attendees: Abram, Anna; Gross, Karas; Tantillo, Andrew; Aguilar, Paul; Pennington, Caitlin; Schipper, Jodi; McSeveney, Megan; Howard, Megan; Hinton, Denise; Shirley, Mayo

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Attachments:

Dr. Hahn Statement as of 2/13 3:55pm
Opening talking points from briefing call today
Full Talking Points Document

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Sent: 2/13/2020 4:04:33 PM
To: Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BL]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Howard, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: Prep for Friday Congressional Phone Briefing on Supply Chain
Attachments: Draft Statement AA.docx021320_CDRHCDCERCFSANORA1515AA (003).docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA .docx
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Subject: Prep for Friday Congressional Phone Briefing on Supply Chain
Attachments: Draft Statement AA.docx021320_CDRHCDERCFSANORA1515AA (003).docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA .docx
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Required Attendees: Abram, Anna; Gross, Karas; Tantillo, Andrew; Aguilar, Paul; Pennington, Caitlin; Schipper, Jodi; McSeveney, Megan; Howard, Megan; Hinton, Denise; Shirley, Mayo; Rath, Prakash (FDA)

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To: Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]; Howard, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]
Subject: RE: Prep for Friday Congressional Phone Briefing on Supply Chain
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Please see the attachments referenced on this call.

From: Black, Jennifer
Sent: Thursday, February 13, 2020 4:28 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: Prep for Friday Congressional Phone Briefing on Supply Chain

Please join this call at 2/13 4:15

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Jennifer R. Black, J.D.

Congressional Affairs Specialist

Office of Legislation

U.S. Food and Drug Administration
Tel: 301-796-9607
jennifer.black@fda.hhs.gov



From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/13/2020 5:19:28 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: Urgent: Information request for ASPR White House Briefing
Attachments: nCOV Supply Chain WH briefing data call 02112020_FDA (002) 515 pm.pptx

One edit in the attached (b)(5)

Internal confidential

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, February 13, 2020 2:13 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing
Importance: High

Anna and Keagan,

Attached is the draft FDA content for ASPR for tomorrow's White House briefing (b)(5)
(b)(5)
(b)(5) After your review, just let me know if you'd like to send the slides back to ASPR or if you'd like me to.

I'm also separately attaching (b)(5)
(b)(5)

Thanks,
Brooke

From: Courtney, Brooke
Sent: Thursday, February 13, 2020 1:37 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Yes, I will send them shortly—I'm in the process of adding the additional information requested below. OCC still needs to review the new information, which I've already sent to them.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Thursday, February 13, 2020 1:33 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Can I see the slides please?

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Thursday, February 13, 2020 12:53 PM

To: Courtney, Brooke <Brooke.Courtnev@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

I haven't heard anything further from the ASPR team so let's just proceed based on what we know and loop back with them.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Thursday, February 13, 2020 10:52 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Hi Anna,

Thank you for the input.

(b)(5)

(b)(5)

Thanks,
Brooke

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Thursday, February 13, 2020 10:47 AM

To: Courtney, Brooke <Brooke.Courtnev@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Plus Keagan

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Thursday, February 13, 2020 8:42 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Subject: FW: Urgent: Information request for ASPR White House Briefing

Importance: High

Hi Anna and Denise,

For your review this morning, attached are the combined FDA comments/edits on (b)(5) for tomorrow's White House meeting. The attached slide deck includes input from (b)(5)

(b)(5) OCC reviewed the content last night.

(b)(5)

(b)(5)

Also, while it's possible FDA could go more in detail with ASPR and CDC during a meeting if needed (b)(5)

(b)(5)

We'd like to return these to ASPR this morning if at all possible.

Thanks!

Brooke

Brooke Courtney, JD, MPH

Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats

Office of the Commissioner

U.S. Food and Drug Administration

301-796-0376 (office) (b)(6) (cell)

brooke.courtney@fda.hhs.gov

From: Courtney, Brooke

Sent: Wednesday, February 12, 2020 6:54 AM

To: Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Brad Leissa <brad.leissa@fda.hhs.gov> <brad.leissa@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>

<Rosemarv.Roberts@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Hornung, Matthew

<Matthew.Hornung@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hashemi, Sema <Sema.Hashemi@fda.hhs.gov>; Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; 'Sutton, William' <William.Sutton@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Ngan, Kelly (Kelly.Ngan@fda.hhs.gov) <KELLY.NGAN@FDA.HHS.GOV>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Block, Frank <Frank.Block@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>

Subject: Urgent: Information request for ASPR White House Briefing

Importance: High

Good morning,

I realize many of you have already received the attached request from HHS/ASPR to review and add (b)(5) (b)(5) for a White House briefing on Friday (this is the same request we mentioned during yesterday afternoon's IMG and AEG meetings). In addition to FDA, other HHS partners (CDC, BARDA, SNS, and ASPR/Division of Critical Infrastructure Protection (CIP)) have been asked to contribute (b)(5) information.

The deadline for FDA to return edits to ASPR is 2:00 pm today. Ideally, we'd like to send a single FDA response back to ASPR, so if you could send me your edits/comments by **12:00 today** that would be super so we can give leadership the opportunity to review before 2:00 if needed since this issue is a very high priority. CDRH, we've seen your great comments about (b)(5) and will work to incorporate those as well.

If you have any questions or concerns, just let Michael or me know.

Many thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) (b)(6) (cell)
brooke.courtney@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/13/2020 8:41:44 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Response requested: Remdesivir 相关信息核实

Any f/u on this during the day?

From: Abdo, Mark <Mark.Abdoo@fda.hhs.gov>
Sent: Thursday, February 13, 2020 8:14 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Remdesivir 相关信息核实

Thank you.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: February 13, 2020 at 07:38:44 EST
To: Abdo, Mark <Mark.Abdoo@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>, Christensen, Lane <Lane.Christensen@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: Remdesivir 相关信息核实

Will do – thanks Mark. Adding John for input as well.

From: Abdo, Mark <Mark.Abdoo@fda.hhs.gov>
Sent: Thursday, February 13, 2020 6:19 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Subject: Fwd: Remdesivir 相关信息核实
Importance: High

Denise, Michael, Anna,
Please see the request below from China's National Medical Products Administration for information on the Remdesivir protocol and advise on a response.
Thanks,
Abdo

From: Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Date: February 13, 2020 at 06:09:09 EST
To: Abdo, Mark <Mark.Abdoo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>

Cc: Salazar, Julio <Julio.Salazar@fda.hhs.gov>, Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>

Subject: Fwd: Remdesivir 相关信息核实

Importance: High

Here is the request by NMPA I referenced in my earlier message.

Lane

----- 原始信息 -----

发件人: 刘袁 <liuyuan@nmpa.gov.cn>

日期: 2020/2/13 17:46 (GMT+08:00)

收件人: "Wang, Lixia (Beijing)" <WangLX@state.gov>

抄送: liujq <liujq@nmpa.gov.cn>, qinxl <qinxl@nmpa.gov.cn>

主题: Remdesivir 相关信息核实

王老师，您好！

有个情况需要请FDA协助确认一下。我们最近获知，吉利德公司的产品瑞德西韦用于治疗新型冠状病毒肺炎的临床方案需要经过美国FDA批准后，方可将产品出口到中国，而FDA已于近日批准了这一临床方案，因此临床试验用瑞德西韦可以向中国出口。

希望FDA驻华办协助核实相关情况。情况紧急，希望今晚能与美国国内联系，明日回复为盼！

Dear Lixia,

We hope FDA China office could do us a favor and help to confirm some information. We were informed that the clinical protocol for Remdesivir treating COVID-19 needs to be approved by FDA. And the product Remdesivir cannot be exported to China until the clinical protocol is approved. It is said that the above-mentioned clinical protocol has been recently approved by FDA and therefore, the product Remdesivir for clinical studies can be exported to China afterwards.

Please help to confirm the above information. Due to the urgency of the situation, we hope you could forward the message to FDA tonight and give us some feedback tomorrow, if possible.

Thank you for your help!

--

LIU Yuan

Division of Bilateral Cooperation, Department of Science, Technology and International
Cooperation

National Medical Products Administration

Tel: 0086 10 88330509

Fax: 0086 10 68337662

刘袁

科技和国际合作司双边合作处

国家药品监督管理局

中国北京西城区展览路北露园1号

电话: 0086 10 88330509

传真: 0086 10 68337662

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 2/14/2020 7:29:00 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Fwd: Urgent: Information request for ASPR White House Briefing
Attachments: Placemats-021320.pptx; HHS 14 Feb COVID_19 PCC Slides Supply Chain v5.pptx
Importance: High

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>

Date: February 13, 2020 at 11:49:16 PM EST

To: Patel, Anita (CDC) <bop1@cdc.gov>

Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, D'alessandro, Maryann M (CDC) <bj5@cdc.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

All-

I feel lousy about how this slide request evolved. I

(b)(5)

(b)(5)

Thanks,

Laura

Laura Kwinn Wolf, Ph.D.

Director, Division of Critical Infrastructure Protection

HHS/ASPR

Unclassified: Laura.wolf@hhs.gov

HSDN: Laura.wolf@dhs.gov

Desk: 202-260-0666

Cell: (b)(6)

From: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Sent: Thursday, February 13, 2020 2:00 PM
To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks all – we sent our deck to Laura with a CC to brooke on another thread.

Laura, Tom, please let know what the questions are that came out of the pre-brief today. We are unclear on a lot regarding this briefing but would like to be sure Dr. Kadlec has what he needs. Also, would be good to share the info that will be shared on Friday with at least agency supply chain leads – want to be sure we are all on the same page.

Also:

CDC and FDA spoke today.

FDA and ASPR spoke today.

CDC and ASPR have not spoken.

Pre-brief was done by ASPR staff with no CDC or FDA staff.

I would like for us to be coordinated on what the SOCOs are. Also we have shared CDC and FDA info with each other. Can someone please share what BARDA and SNS submitted? Sorry if I missed this.

If we can consider adjusting this process in the future that would be great.

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Sent: Thursday, February 13, 2020 10:58 AM
To: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Here is the attachment for Anita, just in case.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health
Office of Policy

U.S. Food and Drug Administration

Tel: 301-796-8924 - Cell:

(b)(6)

jennifer.tomasello@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <b0j5@cdc.gov>

Sent: Thursday, February 13, 2020 10:56 AM

To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Patel, Anita (CDC) <b0j1@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

+ anita patel

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Sent: Thursday, February 13, 2020 10:53 AM

To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <b0j5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Importance: High

Good morning all – sorry we are late with this. Attached is a draft of the talking points you requested. We expect to have updates but hope this is helpful during your prep-in-progress.

Please do let us know if you have any questions; we'll be happy to get additional info. And we appreciate your help making this part of the briefing tomorrow.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health

Office of Policy

U.S. Food and Drug Administration

Tel. 301-796-8924 - Cell (b)(6)

jennifer.tomasello@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Sent: Wednesday, February 12, 2020 4:27 PM

To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Unfortunately the pre-brief for Dr. Kadlec is at 10:30 tomorrow morning, so it would be best to have something, even if draft for that meeting.

Sorry and thank you,

TJ

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 4:24 PM

To: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Good afternoon all – we are working on this. Recognizing this is an urgent request, would it be possible for FDA to provide the talking points mid-day tomorrow? If not, just let us know and we'll make it work.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health

Office of Policy

U.S. Food and Drug Administration

Tel: 301-796-8924 - Cell: (b)(6)

jennifer.tomasello@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 1:35 PM

To: Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>

Cc: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks! We will get these done.

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Date: February 12, 2020 at 1:21:47 PM EST

To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, D'alessandro, Maryann M (CDC) <b.j5@cdc.gov>

Cc: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Thank you, and enjoy your vacation!!!

TJ

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 1:09 PM

To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <b.j5@cdc.gov>

Cc: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

TJ,

I'm about to go on vacation (actually am already officially on leave today packing and running last minute errands) but am still around monitoring emails until this evening.

I am looping in my colleagues from CDRH who can help on the FDA side with some TPs:
Linda Ricci and Jennifer Tomasello.

Linda and Jennifer: the TPs TJ is asking for are intended to accompany / complement the ASPR's briefing to WH on Friday and the slide deck that we noted required edits to reflect proper nomenclature of N95 respirators VS surgical masks. Because we are inundated with work, it might be most efficient to get help from Liz Claverie for these TPs.

I can also forward to you both underseiarate cover the RPD Capabilities Document, a PHEMCE Policy document that was a deliverable of the RPD WG to which we (FDA) participated as well as CDC and CDC NIOSH.

Because there are definitions in there that may be the most authoritative place to go.

Maryann: what do you think?

Suzanne

Suzanne B. Schwartz, MD, MBA

Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)

Center for Devices & Radiological Health

US Food & Drug Administration

Office: 301-796-6937

Mobile: (b)(6)

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Date: February 12, 2020 at 12:41:08 PM EST

To: D'alessandro, Maryann M (CDC) <b.j5@cdc.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Good afternoon,

Would you be able to help with a

(b)(5)

(b)(5)

Thank you.

v/r,

TJ

From: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>

Sent: Tuesday, February 11, 2020 8:38 PM

To: Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Cc: Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC)

<Brooke.Courtnev@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Dowell, Chad (CDC/NIOSH/OD) <crd7@cdc.gov>; Delaney, Lisa (CDC/NIOSH/OD) <lkd2@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Hello all,

I agree with Suzanne regarding using the proper nomenclature and showing a few examples of each device.

Best,

Maryann

Maryann M. D'Alessandro, PhD

Director

HHS/Centers for Disease Control and Prevention (CDC)

National Institute for Occupational Safety & Health (NIOSH)

National Personal Protective Technology Laboratory (NPPTL)

626 Cochran Mill Rd

Building 141, Rm 105

Pittsburgh, PA 15236

Office: (412) 386-4033

Mobile: (b)(6)

bpj5@cdc.gov



From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 7:27 PM

To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Cc: Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <baj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Laura,

For the WH briefing, I think it would be very helpful for the ASPR to show a surgical mask and to show an N95 respirator so that lay folks can see and understand the difference.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Date: February 11, 2020 at 7:21:04 PM EST
To: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, D'alessandro, Maryann M (CDC) <baj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

CDC should weigh in here as well

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 11, 2020 at 7:19:41 PM EST
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, D'alessandro, Maryann M (CDC) <baj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks very much for that clarification!

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov.gov
Desk: 202-260-0666
Cell: (b)(6)

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 7:12 PM
To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtnev@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Subject: Re: Urgent: Information request for ASPR White House Briefing
Importance: High

Tom et al,

CDRH requests that we use the proper nomenclature for N95s as respirators, and not refer to them as N95 'masks'. Surgical masks are very different than surgical N95 respirators and it is a critical distinction to make here so as to avoid confusion or conflating the two.

I think what the ASPR would like to have information on is at the very least the first two buckets but probably the third as well:

1. N95 respirators (have met standard testing requirements for NIOSH approval)
2. N95 surgical respirators (have met standard testing requirements for NIOSH approval for N95s PLUS additional FDA requirements so as to be considered medical devices)
3. Surgical masks - these are not respirators and do not provide the same respiratory protection as respirators.

I'm copying Anita Patel from CDC and Maryann D'Alessandro from NIOSH / NPPTL for their comments since how we communicate around these products has to be consistent and aligned with the guidance that CDC puts out, and using the generic term 'masks' here very much confuses matters.

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Date: February 11, 2020 at 5:46:43 PM EST
To: Patel, Anita (CDC) <bop1@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, McClune, Elizabeth P (CDC) <ynt0@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, FDA Emergency Operations <emergency.operations@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, Ottem, Ronald S (CDC) <rco9@cdc.gov>, Fredenberg, John E (CDC) <dje5@cdc.gov>, Figlio, Joseph (OS) <Joseph.Figlio@hhs.gov>, Rooks, Mercedes (OS) <Mercedes.Rooks@hhs.gov>, Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Angelastro, Michael (OS) <Michael.Angelastro@hhs.gov>
Cc: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>, Adams, Steven

A (CDC) <saa1@cdc.gov>, Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>

Subject: Urgent: Information request for ASPR White House Briefing

Good afternoon,

Dr. Kadlec is briefing the White House this Friday, February 14, on the status (b)(5)

(b)(5)

He has requested specific information on (b)(5)

(b)(5)

Response requested by 1400 Wednesday, Feb 11, 2020. We apologize for the quick deadline and appreciate your efforts to date to gather this information and to help prepare for this briefing.

Please contact me or Laura for more information on this request.

Thank you.

v/r,

CDR Thomas J (TJ) Christl
U.S. Department of Health & Human Services
Assistant Secretary for Preparedness & Response (ASPR)
Office of Security, Intelligence and Information Management
Division of Critical Infrastructure Protection
Office: 202-260-0680
Cell: (b)(6)

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/14/2020 7:50:21 AM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72e34aa78ff3c8ccb59f92ee-MRaza]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]
CC: Burgess, Shelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5beb691d4bac4848945f6039974b29fa-Shelly.Burg]; Windt, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c120697b3879498d8bf3469fe8975fbb-DSW]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts
Attachments: Draft Statement for SH REVIEW 1-SMH comments AA2013ORA_MM.docx

And from me – use whatever works thx

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, February 14, 2020 7:44 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>

Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

A couple of comments from me labeled "FDA" in the comment box. – If you do not hear more from Michael, you can consider it cleared from OCET.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Friday, February 14, 2020 5:26 AM

To: Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>

Subject: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Good morning! The Commissioner reviewed the draft statement on FDA's coronavirus response efforts and asked for some edits to his talking points. The attached version has the edits from the Commissioner, as well as additional edits made to address his comments. ORA already did a quick review last night to help address those edits – thank you! **We are now asking for concurrent ORA, OCC, and OCET review - if possible -by 9am to review and hopefully very quickly finalize these and any additional edits as needed to ensure accuracy. If is not possible to review by 9am could you please flag for this group as soon as possible?** Carol and others in ORA, I have tried to address Carol's edits and respond to any outstanding questions/comments from ORA in the attached and again want to thank you for your help last night. Many thanks to all of your help and please let me know if you have any questions. Thank you!

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/14/2020 7:53:30 AM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Re: Urgent: Information request for ASPR White House Briefing

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: February 14, 2020 at 7:29:04 AM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Fwd: Urgent: Information request for ASPR White House Briefing
Importance: High

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 13, 2020 at 11:49:16 PM EST
To: Patel, Anita (CDC) <bop1@cdc.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

All-

I feel lousy about how this slide request evolved.

(b)(5)

(b)(5)

Thanks,

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov
Desk: 202-260-0666
Cell: (b)(6)

From: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Sent: Thursday, February 13, 2020 2:00 PM
To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks all – we sent our deck to Laura with a CC to brooke on another thread.

Laura, Tom, please let know what the questions are that came out of the pre-brief today. We are unclear on a lot regarding this briefing but would like to be sure Dr. Kadlec has what he needs. Also, would be good to share the info that will be shared on Friday with at least agency supply chain leads – want to be sure we are all on the same page.

Also:

CDC and FDA spoke today.
FDA and ASPR spoke today.
CDC and ASPR have not spoken.
Pre-brief was done by ASPR staff with no CDC or FDA staff.

I would like for us to be coordinated on what the SOCOs are. Also we have shared CDC and FDA info with each other. Can someone please share what BARDA and SNS submitted? Sorry if I missed this.

If we can consider adjusting this process in the future that would be great.

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Sent: Thursday, February 13, 2020 10:58 AM
To: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Here is the attachment for Anita, just in case.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health
Office of Policy

U.S. Food and Drug Administration

Tel: 301-796-8924 - Cell: (b)(6)

jennifer.tomasello@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <boj15@cdc.gov>

Sent: Thursday, February 13, 2020 10:56 AM

To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Patel, Anita (CDC) <boj1@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

+ anita patel

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Sent: Thursday, February 13, 2020 10:53 AM

To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL)

<boj15@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Importance: High

Good morning all – sorry we are late with this. Attached is a draft of the talking points you requested. We expect to have updates but hope this is helpful during your prep-in-progress.

Please do let us know if you have any questions; we'll be happy to get additional info. And we appreciate your help making this part of the briefing tomorrow.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health
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Tel 301-796-8924 - Cell: (b)(6)

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Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Sent: Wednesday, February 12, 2020 4:27 PM

To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Unfortunately the pre-brief for Dr. Kadlec is at 10:30 tomorrow morning, so it would be best to have something, even if draft for that meeting.

Sorry and thank you,

TJ

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 4:24 PM

To: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Good afternoon all – we are working on this. Recognizing this is an urgent request, would it be possible for FDA to provide the talking points mid-day tomorrow? If not, just let us know and we'll make it work.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health

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Tel: 301-796-8924 - Cell: (b)(6)

jennifer.tomasello@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 1:35 PM
To: Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>
Cc: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks! We will get these done.

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Date: February 12, 2020 at 1:21:47 PM EST
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>
Cc: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thank you, and enjoy your vacation!!!
TJ

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 1:09 PM
To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Cc: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

TJ,

(b)(6)

I am looping in my colleagues from CDRH who can help on the FDA side with some TPs:
Linda Ricci and Jennifer Tomasello.

Linda and Jennifer: the TPs TJ is asking for are intended to accompany / complement the ASPR's briefing to WH on Friday and the slide deck that we noted required edits to reflect (b)(5) (b)(5) Because we are inundated with work, it might be most efficient to get help from Liz Claverie for these TPs.

(b)(5)

Because there are definitions in there that may be the most authoritative place to go.

Maryann: what do you think?

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
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From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Date: February 12, 2020 at 12:41:08 PM EST
To: D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Good afternoon,

(b)(5)

Thank you.
v/r,
TJ

From: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Sent: Tuesday, February 11, 2020 8:38 PM
To: Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Dowell, Chad (CDC/NIOSH/OD) <crd7@cdc.gov>; Delaney, Lisa (CDC/NIOSH/OD) <lkd2@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Hello all,

I agree with Suzanne regarding using the proper nomenclature and showing a few examples of each device.

Best,

Maryann

Maryann M. D'Alessandro, PhD
Director
HHS/Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety & Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Rd
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Pittsburgh, PA 15236

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From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 7:27 PM

To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Cc: Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC)

<Brooke.Courtnev@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Laura,

For the WH briefing, I think it would be very helpful for the ASPR to show a surgical mask and to show an N95 respirator so that lay folks can see and understand the difference.

Suzanne B. Schwartz, MD, MBA

Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)

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Mobile: (b)(6)

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Date: February 11, 2020 at 7:21:04 PM EST

To: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Christl, Thomas (OS) <Thomas.Christl@hhs.gov>

Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

CDC should weigh in here as well

Suzanne B. Schwartz, MD, MBA

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Mobile: (b)(6)

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>

Date: February 11, 2020 at 7:19:41 PM EST

To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Christl, Thomas (OS) <Thomas.Christl@hhs.gov>

Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtnev@fda.hhs.gov>, Patel, Anita

(CDC) <bop1@cdc.gov>, D'alessandro, Maryann M (CDC) <bpj5@cdc.gov>

Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks very much for that clarification!

Laura

Laura Kwinn Wolf, Ph.D.

Director, Division of Critical Infrastructure Protection

HHS/ASPR

Unclassified: Laura.wolf@hhs.gov

HSDN: Laura.wolf@dhs.gov.gov

Desk: 202-260-0666

Cell: (b)(6)

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>

Sent: Tuesday, February 11, 2020 7:12 PM

To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Cc: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>;

Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>;

D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>

Subject: Re: Urgent: Information request for ASPR White House Briefing

Importance: High

Tom et al,

(b)(5)

Suzanne

Suzanne B. Schwartz, MD, MBA

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Mobile: (b)(6)

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>

Date: February 11, 2020 at 5:46:43 PM EST

To: Patel, Anita (CDC) <bop1@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, McClune, Elizabeth P (CDC) <ymt0@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, FDA Emergency Operations <emergency.operations@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, Ottem, Ronald S (CDC) <rco9@cdc.gov>, Fredenberg, John E (CDC) <dje5@cdc.gov>, Figlio, Joseph (OS) <Joseph.Figlio@hhs.gov>, Rooks, Mercedes (OS) <Mercedes.Rooks@hhs.gov>, Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Angelastro, Michael (OS) <Michael.Angelastro@hhs.gov>

Cc: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>

Subject: Urgent: Information request for ASPR White House Briefing

Good afternoon,

Dr. Kadlec is briefing the White House this Friday, February 14, on the status (b)(5)

(b)(5)

He has requested specific information on (b)(5)

(b)(5)

Response requested by 1400 Wednesday, Feb 11, 2020. We apologize for the quick deadline and appreciate your efforts to date to gather this information and to help prepare for this briefing.

Please contact me or Laura for more information on this request.

Thank you.

v/r,

CDR Thomas J (TJ) Christl
U.S. Department of Health & Human Services
Assistant Secretary for Preparedness & Response (ASPR)
Office of Security, Intelligence and Information Management
Division of Critical Infrastructure Protection
Office: 202-260-0680
Cell: (b)(6)

From: Black, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AAF8A19F3672492293A7C1B2D1498059-JENNIFER.BL]
Sent: 2/14/2020 9:43:32 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ngan, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7a30838c8bc49428cbbe4959ae8ed6c-NGANK]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
CC: Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: Congressional Briefings for 2/14
Attachments: 2.14.20 SUPPLY CHAIN Talking Points Member meeting for Denise.docx; nCoR 2-14-20 General Talking Points and QnA .docx

Good morning team,

For our prep calls and briefings today, attached are the documents we will be working from. The first attachment includes the supply chain talking points that Denise will read through on the call. The second attachment contains general talking points for any potential questions.

We will discuss the run of show at our 10:30 internal prep call, including what SMEs should be prepared to discuss. Please be prepared to discuss updates on your relevant medical products.

Thank you all and see/ talk to you soon!

Jen

From: Black, Jennifer

Sent: Thursday, February 13, 2020 6:25 PM

To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>

Cc: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: Congressional Briefings for 2/14

Hi team coronavirus,

We just had a prep with some of you this evening and we want to thank you for being willing to join us on such short notice. To recap, we have two Congressional briefings that have been scheduled for tomorrow. We will be briefing Education & Labor and Energy & Commerce at 12:00 and Sen. Cornyn staff at 2:00.

If you were not in the prep today, you were identified as key staff that we should have at the briefings tomorrow to ensure all offices are represented. We are having a prep with ASPR at 10 am tomorrow, followed by an internal FDA prep at 10:30. We will send you all the invites to these. We are waiting for the Commissioner's statement to be fully cleared until we send around the meeting documents for tomorrow, but we will either send the updated versions around late tonight or tomorrow morning. The documents have already been cleared and RADM Hinton's opening statements will generally come from the Commissioner's statement.

We will be in touch soon with the meeting invites and updated documents. Please reach out to any of our team in OL with any questions or concerns.

Thank you for your continued hard work!

Jen

2/14/2020 Interagency Phone Briefing Schedule

10:00-10:30; Prep with ASPR

10:30-11:00; Internal FDA prep

12:00-12:30 pm; Supply Chain Efforts with Education & Labor and Energy & Commerce

FDA SMEs:

- OCS: Denise Hinton
- OMA: Megan McSeveney
- OCET: Liz Sadove
- CDER: Val Jensen, Paras Patel, Rosemary Roberts, Kelly Ngan
- CBER: David Rouse, David Cho
- CDRH: Jennifer Tomasello, Heather Aglar
- ORA: Mike Rogers
- OCC: Don Beers, Dinesh Kumar

2:00-2:30pm; Supply Chain Briefing with Cornyn Staff: Jeff Last

FDA SMEs:

- OCS: Denise Hinton
- OCET: Brooke Courtney
- OMA: Megan McSeveney
- CDER: Val Jensen, Paras Patel, Rosemary Roberts, Kelly Ngan
- CBER: David Rouse, David Cho
- CDRH: Jennifer Tomasello, Heather Aglar
- ORA: Mike Rogers
- OCC: Don Beers, Dinesh Kumar

Jennifer R. Black, J.D.

Congressional Affairs Specialist

Office of Legislation

U.S. Food and Drug Administration

Tel: 301-796-9607

jennifer.black@fda.hhs.gov



From: McSeveney, Megan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]
Sent: 2/14/2020 12:23:14 PM
To: Thomson, Kyle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d798c4005b6492da7e6f4cac6c2cc63-Kyle.Thomso]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Cave, Carol [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9a314ec380042d890e8976202f6a91b-Carol.Cave]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; McMeekin, Judith [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d824f07697784fcb9ece28cbba07102b-MCMEEKINJ]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Humbert, Jason [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e25fbc271284103869c8e8df8247417-Humbert]
CC: Burgess, Shelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5beb691d4bac4848945f6039974b29fa-Shelly.Burg]; Windt, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c120697b3879498d8bf3469fe8975fbb-DSW]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddb3e3e5ffe3d-Heather.Jan]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Lynch, Kara P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=815fc647fca54af2b8b57df1460f3a82-KLYNCH]; Franz, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cd5d368da9f4467996f569a6229751d6-Lauren.Fran]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]
Subject: NEW - Latest version COVID19 statement - Commissioner's statement re: FDA outbreak coronavirus response efforts
Attachments: CLEANDRFTStatement 0957SHAAOCETORAOCCAA 1205pm.docx

Hi all – attached is the latest version of this statement with final input from the Commissioner and Anna that went to HHS for final clearance through HHS and the interagency. While this will get a final proof, I hope that I won't need to run any more edits by you all. I greatly appreciate all the help. Thank you again!

Megan McSeveney

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-4514/Cel: (b)(6)

Megan.McSeveney@fda.hhs.gov



From: Thomson, Kyle <Kyle.Thomson@fda.hhs.gov>

Sent: Friday, February 14, 2020 10:30 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>

Subject: RE: Latest version COVID19 statement please review by 10:30 - Commissioner's statement re: FDA outbreak coronavirus response efforts

Megan,

Thanks, you did indeed copy the right Kyle from OCC. OCC clears the green highlighted language. Thank you to the task force and others in OCC for their quick turnaround yesterday.

Kyle

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Friday, February 14, 2020 10:12 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Thomson, Kyle <Kyle.Thomson@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather

<Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>

Subject: Latest version COVID19 statement please review by 10:30 - Commissioner's statement re: FDA outbreak coronavirus response efforts

Hi all – lots of edits this am. Thank you all! Attached is a version for review that has edits incorporated. We are also waiting to hear if HHS will have edits to reconcile. Anna is planning to review this after 10:30 so any comments before 10:30 would be much appreciated. Attaching the same document in tracked and clean versions. Jason and OCC, can you please review the task force efforts I have added and highlighted in green and make sure that I am not crossing the line /that this can be shared. I would love to highlight your work! Kyle, I'm not sure if I identified the right Kyle from OCC working on this – if not – my apologies! Thank you!

Megan McSeveney

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov



From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Friday, February 14, 2020 9:06 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>

Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

(b)(5)

(b)(5)

Happy to help with that.

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Friday, February 14, 2020 8:58 AM

To: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke

<Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>

Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Thank you all- I'll incorporate this in and send back shortly as we keep this moving. Thanks!

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Date: February 14, 2020 at 8:52:15 AM EST

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Raza, Mark <Mark.Raza@fda.hhs.gov>, Cave, Carol <Carol.Cave@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Laska, Susan F <Susan.Laska@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>, Windt, David <David.Windt@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Lynch, Kara P <Kara.Lynch@fda.hhs.gov>, Franz, Lauren <Lauren.Franz@fda.hhs.gov>

Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

(b)(5)

(b)(5)

Sorry for the

confusion.

Thanks very much-
Dinesh

Dinesh Kumar

Office of the Chief Counsel, FDA
Food and Drug Division, OGC/HHS
White Oak Building 32, Room 4377
10903 New Hampshire Ave.
Silver Spring, MD 20993
T. 240.402.0372

C: (b)(6)

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From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>

Sent: Friday, February 14, 2020 8:48 AM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith

<Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>
Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Hi all- I'll start working on getting the edits from Mark incorporated. Thank you!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 14, 2020 at 8:44:54 AM EST
To: Raza, Mark <Mark.Raza@fda.hhs.gov>, Cave, Carol <Carol.Cave@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Laska, Susan F <Susan.Laska@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>, Windt, David <David.Windt@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Lynch, Kara P <Kara.Lynch@fda.hhs.gov>, Franz, Lauren <Lauren.Franz@fda.hhs.gov>
Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Risk based is also for food per FSMA, no?

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Date: February 14, 2020 at 8:43:44 AM EST
To: Cave, Carol <Carol.Cave@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>, Laska, Susan F <Susan.Laska@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>, Windt, David <David.Windt@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Lynch, Kara P <Kara.Lynch@fda.hhs.gov>, Franz, Lauren <Lauren.Franz@fda.hhs.gov>
Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Apologies – for this not being in the document:

(b)(5)

From: Cave, Carol <Carol.Cave@fda.hhs.gov>

Sent: Friday, February 14, 2020 7:56 AM

To: Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>

Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Agree with Michael. Megan added language to address your comments. Also included the work of the Health Fraud unit so show FDA response.

From: Rogers, Michael <Michael.Rogers@fda.hhs.gov>

Sent: Friday, February 14, 2020 7:51 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather

<Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>
Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

ORA clears. I agree with the comments about not including the inspection numbers for the cancelled for-cause and surveillance inspections if we aren't prepared to address both types. Let's just use the term "inspections" since I'm not sure the public understands the difference between for-cause and surveillance inspections.

Michael C. Rogers, MS
Assistant Commissioner for Human and Animal Food Operations
FDA/ORO/OHAFO
240-402-4029

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 14, 2020 5:26 AM
To: Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Subject: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Good morning! The Commissioner reviewed the draft statement on FDA's coronavirus response efforts and asked for some edits to his talking points. The attached version has the edits from the Commissioner, as well as additional edits made to address his comments. ORA already did a quick review last night to help address those edits – thank you! **We are now asking for concurrent ORA, OCC, and OCET review - if possible -by 9am to review and hopefully very quickly finalize these and any additional edits as needed to ensure accuracy. If is not possible to review by 9am could you please flag for this group as soon as possible?** Carol and others in ORA, I have tried to address Carol's edits and respond to any outstanding questions/comments from ORA in the attached and again want to thank you for your help last night. Many thanks to all of your help and please let me know if you have any questions. Thank you!

From: Abdo, Mark [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DCA42E5F1795433C9DF447F8F11BC80E-MARK.ABDOO]
Sent: 2/14/2020 3:34:48 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]
CC: Ross, Bruce [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae281dfd2164cb8959133dfe0026cee-Bruce.Ross]; Christensen, Lane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=785d122761ad43b9b2cd49ffc5a16b66-CHRISTENSL]
Subject: RE: Remdesivir 相关信息核实

Works for me.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 14, 2020 3:31 PM
To: Abdo, Mark <Mark.Abdo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Subject: RE: Remdesivir 相关信息核实

Hi – I believe this is referring to the export issue related to remdesivir for the clinical trial in China, which has been resolved and the product exported. It might be best to refer it to the HHS SOC for response...?

From: Abdo, Mark <Mark.Abdo@fda.hhs.gov>
Sent: Thursday, February 13, 2020 6:19 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Subject: Fwd: Remdesivir 相关信息核实
Importance: High

Denise, Michael, Anna,
Please see the request below from China's National Medical Products Administration for information on the Remdesivir protocol and advise on a response.
Thanks,
Abdo

From: Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Date: February 13, 2020 at 06:09:09 EST
To: Abdo, Mark <Mark.Abdo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Cc: Salazar, Julio <Julio.Salazar@fda.hhs.gov>, Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>
Subject: Fwd: Remdesivir 相关信息核实
Importance: High

Here is the request by NMPA I referenced in my earlier message.

Lane

----- 原始信息 -----

发件人: 刘袁 <liuyuan@nmpa.gov.cn>

日期: 2020/2/13 17:46 (GMT+08:00)

收件人: "Wang, Lixia (Beijing)" <WangLX@state.gov>

抄送: liujq <liujq@nmpa.gov.cn>, qinxl <qinxl@nmpa.gov.cn>

主题: Remdesivir 相关信息核实

王老师，您好！

有个情况需要请FDA协助确认一下。我们最近获知，吉利德公司的产品瑞德西韦用于治疗新型冠状病毒肺炎的临床方案需要经过美国FDA**批准后，方可将产品出口到中国，而FDA已于近日批准了**这一临床方案，因此临床试验用瑞德西韦可以向中国出口。

希望FDA驻华办协助核实相关情况。情况紧急，希望今晚能与美国国内联系，明日回复为盼！

Dear Lixia,

We hope FDA China office could do us a favor and help to confirm some information. We were informed that the clinical protocol for Remdesivir treating COVID-19 needs to be approved by FDA. And the product Remdesivir cannot be exported to China until the clinical protocol is approved. It is said that the above-mentioned clinical protocol has been recently approved by FDA and therefore, the product Remdesivir for clinical studies can be exported to China afterwards.

Please help to confirm the above information. Due to the urgency of the situation, we hope you could forward the message to FDA tonight and give us some feedback tomorrow, if possible.

Thank you for your help!

--

LIU Yuan

Division of Bilateral Cooperation, Department of Science, Technology and International
Cooperation

National Medical Products Administration

Tel: 0086 10 88330509

Fax: 0086 10 68337662

刘袁

科技和国际合作司双边合作处

国家药品监督管理局

中国北京西城区展览路北露园1号

电话: 0086 10 88330509

传真: 0086 10 68337662

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/14/2020 5:12:07 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; McSeveney, Megan [Megan.McSeveney@fda.hhs.gov]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]; Jensen, Valerie E [Valerie.Jensen@fda.hhs.gov]; Patel, Paras M [Paras.Patel@fda.hhs.gov]; Roberts, Rosemary [Rosemary.Roberts@fda.hhs.gov]; Ngan, Kelly [Kelly.Ngan@fda.hhs.gov]; Rouse, David [David.Rouse@fda.hhs.gov]; Tomasello, Jennifer [Jennifer.Tomasello@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]; Kumar, Dinesh [Dinesh.Kumar@fda.hhs.gov]; Beers, Donald [Donald.Beers@fda.hhs.gov]; Rogers, Michael [Michael.Rogers@fda.hhs.gov]; Shirley, Mayo [Mayo.Shirley@fda.hhs.gov]; Pennington, Caitlin [Caitlin.Pennington@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Black, Jennifer [Jennifer.Black@fda.hhs.gov]; Schipper, Jodi [jodi.schipper@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Aguilar, Paul [Paul.Aguilar@fda.hhs.gov]; 2019-nCoV FDA IMG Planning [2019-nCoVFDAIMGPlanning@fda.hhs.gov]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Anderson, Erika [Erika.Anderson@fda.hhs.gov]; Romano, Lisa M. [Lisa.Romano@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Mair, Michael [Michael.Mair@fda.hhs.gov]
Subject: prep HELP briefing - COVID 19 Supply chain
Attachments: 2.14.20 SUPPLY CHAIN Talking Points Member meeting for Denise.docx; nCoR 2-14-20 General Talking Points and QnA .docx
Location: WO32 - 1367 (EOC conference room)
Start: 2/18/2020 10:30:00 AM
End: 2/18/2020 11:00:00 AM
Show Time As: Tentative

Required Attendees: Hinton, Denise; McSeveney, Megan; Sadove, Elizabeth; Courtney, Brooke; Jensen, Valerie E; Patel, Paras M; Roberts, Rosemary; Ngan, Kelly; Rouse, David; Tomasello, Jennifer; Agler, Heather L; Kumar, Dinesh; Beers, Donald; Rogers, Michael; Shirley, Mayo; Pennington, Caitlin; Gross, Karas; Black, Jennifer; Schipper, Jodi; Tantillo, Andrew; Aguilar, Paul; 2019-nCoV FDA IMG Planning; Abram, Anna; Anderson, Erika; Romano, Lisa M.; Cho, David S (CBER); Mair, Michael

- The attached TP's may change a bit
- <http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx>
- Includes draft responses to questions, which SME's will convey verbally

Includes QA from ASPR

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From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/14/2020 5:12:07 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ngan, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7a30838c8bc49428cbbe4959ae8ed6c-NGANK]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079b1f5a01744bd94687d6718ca4c42-Donald.Beer]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; 2019-nCoV FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Romano, Lisa M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9653957f210f4febb1c12c64207346d4-LROMANO]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group

CC: (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Arsenault, Sam
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f4304f5e82a4bb88d9210e1aa7ecc5b-Samuel.Arse]; Raghuwanshi, Rakesh
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Hodnette, Jonathan
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Price, William
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]

Subject: prep HELP briefing - COVID 19 Supply chain
Attachments: 2.18.20 SUPPLY CHAIN Talking Points Member meeting for Denise.docx; nCoR 2-18-20 General Talking Points and QnA .docx; 2.18.20 Senate HELP Bipar QnA.docx
Location: WO32 - 1367 (EOC conference room)
Start: 2/18/2020 10:30:00 AM
End: 2/18/2020 11:00:00 AM
Show Time As: Busy

Required Attendees: Hinton, Denise; McSeveney, Megan; Sadove, Elizabeth; Courtney, Brooke; Jensen, Valerie E; Patel, Paras M; Roberts, Rosemary; Ngan, Kelly; Rouse, David; Tomasello, Jennifer; Agler, Heather L; Kumar, Dinesh; Beers, Donald; Rogers, Michael; Shirley, Mayo; Pennington, Caitlin; Gross, Karas; Black, Jennifer; Schipper, Jodi; Tantillo, Andrew; Aguilar, Paul; 2019-nCoV FDA IMG Planning; Abram, Anna; Anderson, Erika; Romano, Lisa M.; Cho, David S (CBER); Mair, Michael

Hello,

We made minor tweaks to the attached documents, and will talk about these and the run of show in a few minutes. We'll bring copies.

Thanks,
Prakash

- The attached TP's may change a bit
- <http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx>
- Includes draft responses to questions, which SME's will convey verbally

Includes QA from ASPR

-- Do not delete or change any of the following text. --

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/14/2020 6:05:22 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: F/u re: Remdesivir 相关信息核实

From: Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Sent: Friday, February 14, 2020 5:22 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Subject: RE: Remdesivir 相关信息核实

Quick question,

Wasn't the original ask just wanting a confirmation from FDA that the protocol has been approved and product cleared for export? The problem being the expeditious manner that really caught NMPA off guard because FDA took much less than 30 days to review and make a determination. It may have been cleared to leave the US but it is being held up by Chinese authorities.

Lane

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 14, 2020 3:31 PM
To: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Subject: RE: Remdesivir 相关信息核实

Hi – I believe this is referring to the export issue related to remdesivir for the clinical trial in China, which has been resolved and the product exported. It might be best to refer it to the HHS SOC for response...?

From: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>
Sent: Thursday, February 13, 2020 6:19 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
Cc: Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Subject: Fwd: Remdesivir 相关信息核实
Importance: High

Denise, Michael, Anna,
Please see the request below from China's National Medical Products Administration for information on the Remdesivir protocol and advise on a response.

Thanks,
Abdoo

From: Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Date: February 13, 2020 at 06:09:09 EST
To: Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Cc: Salazar, Julio <Julio.Salazar@fda.hhs.gov>, Gabrel, Celia <Celia.Gabrel@fda.hhs.gov>
Subject: Fwd: Remdesivir 相关信息核实
Importance: High

Here is the request by NMPA I referenced in my earlier message.

Lane

----- 原始信息 -----

发件人: 刘袁 <liuyuan@nmpa.gov.cn>
日期: 2020/2/13 17:46 (GMT+08:00)
收件人: "Wang, Lixia (Beijing)" <WangLX@state.gov>
抄送: liujq <liujq@nmpa.gov.cn>, qinxl <qinxl@nmpa.gov.cn>
主题: Remdesivir 相关信息核实

王老师，您好！

有个情况需要请FDA协助确认一下。我们最近获知，吉利德公司的产品瑞德西韦用于治疗新型冠状病毒肺炎的临床方案需要经过美国FDA**批准后，方可将产品出口到中国，而FDA已于近日批准了**这一临床方案，因此临床试验用瑞德西韦可以向中国出口。

希望FDA驻华办协助核实相关情况。情况紧急，希望今晚能与美国国内联系，明日回复为盼！

Dear Lixia,

We hope FDA China office could do us a favor and help to confirm some information. We were informed that the clinical protocol for Remdesivir treating COVID-19 needs to be approved by FDA. And the product Remdesivir cannot be exported to China until the clinical protocol is approved. It is said that the above-mentioned clinical protocol has been recently approved by FDA and therefore, the product Remdesivir for clinical studies can be exported to China afterwards.

Please help to confirm the above information. Due to the urgency of the situation, we hope you could forward the message to FDA tonight and give us some feedback tomorrow, if possible.

Thank you for your help!

--

LIU Yuan

Division of Bilateral Cooperation, Department of Science, Technology and International Cooperation

National Medical Products Administration

Tel: 0086 10 88330509

Fax: 0086 10 68337662

刘袁

科技和国际合作司双边合作处

国家药品监督管理局

中国北京西城区展览路北露园1号

电话: 0086 10 88330509

传真: 0086 10 68337662

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/14/2020 6:09:20 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]
Subject: RE: SITREP
Attachments: 17_2019-nCoV Outbreak_FDA SITREP_14 February 2020.docx

Use this version thx

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Friday, February 14, 2020 6:08 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Measer, Gregory <Gregory.Measer@fda.hhs.gov>
Subject: Re: SITREP

Will review shortly

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: February 14, 2020 at 6:00:48 PM EST
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Measer, Gregory <Gregory.Measer@fda.hhs.gov>
Subject: SITREP

Sorry it's late...

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/17/2020 8:02:36 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Fwd: CDC 2019-nCoV Test Update

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 17, 2020 at 7:44:18 AM EST
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 17, 2020 at 6:51:39 AM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks Jeff, looking towards today's update.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review

(b)(5)

(b)(5)

Jeff

Internal confidential

From: Ferro, Phil J. EOP/NSC; (b)(6)
Sent: 2/17/2020 9:58:19 AM
To: Ferro, Phil J. EOP/NSC; (b)(6); DL NSC Defense; DL NSC Legal; DL NSC NSA FO Staff; DL NSC STRATCOM; Droegemeier, Kelvin K. EOP/OSTP; Daravi, Kamran S. EOP/WHO; Grewe, Brenda L. EOP/NSC; Deere, Judd P. EOP/WHO; Ditto, Jessica E. EOP/WHO; Yanick, Brittany M. EOP/WHO; Hayes, Bradley F. EOP/OMB; Smith, Gregory L. EOP/WHO; Doster, Kim M. EOP/OSTP; Gastfriend, Daniel Z. EOP/OMB; Baum, Kristina R. EOP/OSTP; Bicket, Mark C. EOP/OSTP; Blair, Robert B. EOP/WHO; Bonyun, Sean C. EOP/OSTP; Butterfield, Nicholas W. EOP/WHO; Campana, Alexandra D. EOP/WHO; Grogan, Joseph J. EOP/WHO; Hudson, Renee R. EOP/WHO; Jack, Brian T. EOP/WHO; Kan, Derek T. EOP/OMB; Kratsios, Michael J. EOP/OSTP; Lattimore, Tracie B. EOP/OSTP; Lin, Merry S. EOP/WHO; McKenna, Michael A. EOP/WHO; Merkel, Theo W. EOP/WHO; Miles, Aaron R. EOP/OSTP; Olmem, Andrew J. EOP/WHO; Pataki, Tim A. EOP/WHO; Ray, Paul J. EOP/OMB; Wong, Anna W. EOP/CEA; Walters, William; Bonner, Maria K. EOP/WHO; Sinclair, Michael R. EOP/NSC; DL NSC WMD; Cetron, Martin (CDC); gary.c.rasicot; (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA); Firoved, Aaron; Limage, Julia; Seffel, Gary A. EOP/NSC; Redfield, Robert R (CDC); Waterman, Paige E. EOP/OSTP; Waterman, Elijah J. EOP/NSC; Watson, Ian D. EOP/OSTP; Biles, Amber D CDR USN OSD OUSD POLICY (USA); Fauci, Anthony S (NIH); Marston, Hilary D (NIH); Marks, Peter; Mair, Michael; Kadlec, Robert P (OS); Kerr, Lawrence (OS); Grigsby, Garrett G (OS); Disbrow, Gary (OS); Tobert, Gwen M; Scovitch, Joseph R; Costello, Kelly E; DL NSC IO; DL NSC Asia; DL NSC Press; DL NSC Resilience; DL NSC HSA FO Staff; DL NSC Legislative; DL NSC BATS; Redd, John T (OS); Cornett, Elizabeth A CIV (USA); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA); Gulati, Neetu; Liebschutz, Jennifer E. EOP/OMB; Farquharson, Christine E. EOP/OMB; Imize@usaid.gov; jslootnick@usaid.gov; Kendra Chittenden; Boney, Virginia M. EOP/WHO; Tully, Ryan M. EOP/NSC; Frater, Eric M; Christ, Katelyn E. EOP/NSC; Weinberger, Collin (OS); Landrum, Ryan P. EOP/NSC; Rault, Nick M. EOP/NSC; Hanna, Cory M. EOP/NSC; Burton, Nicholas S. EOP/OMB; Garufi, Marc A. EOP/OMB; Mroz, Sara K. EOP/NSC; Troye, Olivia EOP/NSC; Carlson, Eric J; McGowan, Robert K (CDC); Lowry, Patrick J. EOP/NSC; Cartin, Josh M. EOP/NSC; Kanapathy, Ivan J. EOP/NSC; Elvander, Erika (OS); Cavanaugh, Brian J. EOP/NSC; Bakewell, Richard A; Thomas, Gloria D (OS); Butler, Jay C (CDC); Bright, Rick (OS); Ruggiero, Anthony J. EOP/NSC; Brett Armstrong - D1R; paul.detitta@gsa.gov; Marwaha, Brianna C; Carstens, Virgil W; Hassell, David (OS); McMillin, Virginia D. EOP/WHO; Telle, Adam R. EOP/WHO; Sugarman, AJ J. EOP/WHO; Planning, David M. EOP/WHO; Feddersen, Brett (FAA); Padget, Larry G; Greene Richard S. (GH/HIDN) [USAID] (rgreene@usaid.gov); Baehr, James S. EOP/WHO; Magrino, Christopher; debbie.w.seguin; (b)(6); william.ferrara; (b)(6); Tobin, Elizabeth D. EOP/NSC; Jonas, Seth H. EOP/NSC; Martin, Gregory J; Music, Chris G. EOP/OMB; Ali, Nausher; Burris, Meghan K. EOP/WHO; Henning, Alexa A. EOP/WHO; Daravi, Roma S. EOP/WHO; Horstman, John H. EOP/WHO; MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA); Wilson, John Mark M. EOP/NSC; Martin, Michael E. EOP/NSC; donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC; Gray, Alexander B. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Ulyot, John L. EOP/NSC; Stufft, Julie M. EOP/NSC; Stimson, Brian (OS); Browne, Lisa Y. EOP/NSC; Davis, May M. EOP/WHO; Lekan, Scott M (ACF); Chafin, Kelly B. EOP/NSC; Bailey, Drew M. EOP/OMB; Thallam, Satya P. EOP/OMB; Allen, Ronald G. EOP/NSC; Schuchat, Anne (CDC); Bain, Ally P. EOP/OMB; Schmoyer, Michael (OS); Lepore, Loretta A (CDC); alexandra.doumas@usdoj.gov; Hinton, Denise; Champagne, Joshua D. EOP/NSC; Mesquita, Mario M; Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA); DL Chief of Staff Office; (b)(6); (b)(6); Ash, Deborah J. EOP/NSC; Reilly, Tom M. EOP/OMB; Havranek, John; Dumm, Christopher M; FORET, VERNON T; Ellis, Michael J. EOP/WHO; Blue, Matthew (ODAG); Decker, Matthew G. EOP/NSC; JACKSTA, LINDA L; Parra, Yolanda A; Carter, Hillary H. EOP/NSC; Galkowski, James J. EOP/WHO; Tokumasu de Silva, Miriam E; Doyle, Emma K. EOP/WHO; Lason, Adam J. EOP/NSC; McPheeME; (b)(6); Carson, Tracy L (Geneva); Bibo, David

Subject: SARS-CoV-2 (b)(5)
Location: EEOB Room 374 SMS Large and SVTC

Start: 2/18/2020 2:30:00 PM
End: 2/18/2020 3:50:00 PM
Show Time As: Tentative

Dear Colleagues,

Please accept this meeting invite for a (b)(5) tomorrow afternoon. Given the dynamic nature of the epidemic and the number of ongoing work streams across the USG, there may nor may not be a need for this meeting tomorrow and we will let everyone know ASAP. Also, the content for the agenda is evolving and we will distribute and agenda ASAP.

(b)(5)

Participants are expected to attend in person. With exception of CDC Atlanta and NIAD, SVTC connection will be in listen only mode, though D/A are welcome to have additional participants listen in via SVTC for SA. Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

The classification of this meeting will by U//FOUO)

Please use the WAVES link to register for attendance. (b)(6)

We sincerely thank everyone for their flexibility as we address this complex and rapidly evolving issue, and are very appreciative of the huge effort being put forth.

Best Regards,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/17/2020 9:58:47 AM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Odf896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasico (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Of1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2b83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6)

(b)(6) Frater, Eric M (b)(6) Christ, Katelyn E. EOP/NSC
(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Troye, Olivia
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EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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paul.detitta@gsa.gov; Marwaha, Brianna C (b)(6); Carstens, Virgil W (b)(6)
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EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Sugarman,
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(b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J
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(b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John
H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
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(b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
EOP/NSC (b)(6) Ulyyot, John L. EOP/NSC (b)(6) Stuftt, Julie M.
EOP/NSC (b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b)(6) Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
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P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-acs1-cd]; Bain, Ally P. EOP/OMB
(b)(6) Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office
(b)(6) (b)(6) (b)(6) Ash, Deborah J. EOP/NSC
(b)(6) Reilly, Tom M. EOP/OMB (b)(6) Havranek, John
(b)(6) Dumm, Christopher M (b)(6) FORET, VERNON T

(b)(6) Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew
(ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC (b)(6) JACKSTA,
LINDA L (b)(6) Parra, Yolanda A (b)(6) Carter, Hillary H. EOP/NSC
(b)(6) Galkowski, James J. EOP/WHO (b)(6) Tokumasu de
Silva, Miriam E (b)(6) Doyle, Emma K. EOP/WHO (b)(6) Lason, Adam
J. EOP/NSC (b)(6); McPheeME (b)(6) Carson, Tracy L (Geneva) (b)(6)
Bibo, David (b)(6)

Subject: SARS-CoV-2 (b)(5)
Location: EEOB Room 374 SMS Large and SVTC

Start: 2/18/2020 2:30:00 PM
End: 2/18/2020 3:50:00 PM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

Please accept this meeting invite for a (b)(5) tomorrow afternoon. Given the dynamic nature of the epidemic and the number of ongoing work streams across the USG, there may nor may not be a need for this meeting tomorrow and we will let everyone know ASAP. Also, the content for the agenda is evolving and we will distribute and agenda ASAP.

(b)(5)

Participants are expected to attend in person. With exception of CDC Atlanta and NIAD, SVTC connection will be in listen only mode, though D/A are welcome to have additional participants listen in via SVTC for SA. Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

The classification of this meeting will by U//FOUO)

Please use the WAVES link to register for attendance. <https://events.whitehouse.gov/?rid=KQCRWDJ2K8>

We sincerely thank everyone for their flexibility as we address this complex and rapidly evolving issue, and are very appreciative of the huge effort being put forth.

Best Regards,

Phil

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To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abced4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Sefel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden [kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6)

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J. EOP/NSC (b)(6); Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
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(b)(6); Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J
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EOP/NSC (b)(6); Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(b)(6); Davis, May M. EOP/WHO (b)(6); Lekan, Scott M (ACF)
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EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6); Thallam, Satya
P. EOP/OMB (b)(6); Allen, Ronald G. EOP/NSC (b)(6); Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
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Silva, Miriam E (b)(6); Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam
J. EOP/NSC (b)(6); McPheeME (b)(6); Carson, Tracy L (Geneva) (b)(6)
Bibo, David (b)(6)

Subject: SARS-CoV-2 (b)(5)
Location: EEOB Room 374 SMS Large and SVTC
Start: 2/18/2020 2:30:00 PM
End: 2/18/2020 3:50:00 PM
Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

Please accept this meeting invite for a (b)(5) tomorrow afternoon. Given the dynamic nature of the epidemic and the number of ongoing work streams across the USG, there may nor may not be a need for this meeting tomorrow and we will let everyone know ASAP. Also, the content for the agenda is evolving and we will distribute and agenda ASAP.

(b)(5)

Participants are expected to attend in person. With exception of CDC Atlanta and NIAD, SVTC connection will be in listen only mode, though D/A are welcome to have additional participants listen in via SVTC for SA. Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

The classification of this meeting will by U//FOUO)

Please use the WAVES link to register for attendance. (b)(6)

We sincerely thank everyone for their flexibility as we address this complex and rapidly evolving issue, and are very appreciative of the huge effort being put forth.

Best Regards,

Phil

From: Jones, Estella [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99A7F2BD273D42E18320F0667688B0C1-ESTELLA.JON]
Sent: 2/17/2020 1:56:52 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: 2019-nCoV regulatory science gaps quad charts
Attachments: COVIC-19 Reg Sci Request.docx

Importance: High

FYI (b)(5)

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Monday, February 17, 2020 12:18 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps quad charts
Importance: High

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Saturday, February 15, 2020 5:35 PM
To: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Cc: Orr, Robert <Robert.Orr@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps quad charts
Importance: High

Hi. Apologies if I was not clear on the level of detail that is needed (b)(5)

(b)(5)

I need to provide to OB by noon Tuesday. Please review the attached and send thoughts and info ASAP. I can work with Center SMEs if need be but would like you to take another stab at it first.

Please let me know when u will be able to get something back to me as I have a zillion things to do and need to plan for getting this done. Thx

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Friday, February 14, 2020 6:21 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Cc: Orr, Robert <Robert.Orr@fda.hhs.gov>
Subject: Fwd: 2019-nCoV regulatory science gaps quad charts

(b)(5) Not sure if you've already sent the request forward.

Please let me know if there is any additional information needed.

From: Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>

Date: February 14, 2020 at 5:53:48 PM EST

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>, MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>

Cc: Anderson, Lori (Henry) <Lori.Anderson@fda.hhs.gov>, CBER OM/BAFB <CBEROMBABF@fda.hhs.gov>, Leary, Mary <Mary.Leary@fda.hhs.gov>, Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps quad charts

Tracy,

Sorry for the late email.

(b)(5)

(b)(5)

let me know if you have any questions.

(b)(5)

Thank you and have a nice weekend,
Emily

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 5:31 PM

To: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>

Cc: Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Anderson, Lori (Henry) <Lori.Anderson@fda.hhs.gov>; CBER OM/BAFB <CBEROMBABF@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps quad charts

Tracy,

I attached the wrong version of the word document. That's our internal tracking sheet. Please use this for your purposes.

Thanks,
Carolyn

From: Wilson, Carolyn

Sent: Wednesday, February 12, 2020 5:30 PM

To: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>

Cc: Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Anderson, Lori (Henry) <Lori.Anderson@fda.hhs.gov>; CBER OM/BAFB <CBEROMBABF@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps quad charts

Tracy,

Attached is a one-page summary of the quad charts that we received:

(b)(5)

(b)(5)

(b)(5)

Please let us know if you need any additional information to support this.

Thank you,

Carolyn

(b)(5)

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>

Sent: Wednesday, February 12, 2020 4:37 PM

To: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemarv.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>

Cc: Orr, Robert <Robert.Orr@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: FW: 2019-nCoV regulatory science gaps quad charts

Ladies and Gentlemen,

While we understand everyone is very busy with CoV-related activities, we wanted to follow up on the status of the quad charts discussed last Monday!

(b)(5)

(b)(5)

Since this information is being requested by COB

today, it would be very helpful if you forward the quad charts received to date along with estimated total costs at your earliest convenience.

Sincere apologies for the short turnaround time. Any information you can provide to support this request is greatly appreciated.

Best regards,

Tracy

Tracy MacGill, Ph.D.
CAPT, USPHS
Director, MCM Regulatory Science
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
White Oak, Bldg 1, Rm 4315B
10903 New Hampshire Ave

Silver Spring, MD 20993
Ph: 301-796-1366
Fax: 301-847-3536

From: Fisher, Robert

Sent: Wednesday, February 5, 2020 12:14

To: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>

Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>

Subject: 2019-nCoV regulatory science gaps

Takeaways from Monday's meeting on regulatory science gaps:

(b)(5)

Please let me know if I've omitted anything....

Best,
Robert

Robert W. Fisher, Ph.D.

Senior Advisor for CBRN and Pandemic Influenza

Office of Counterterrorism and Emerging Threats (OCET)

Office of the Chief Scientist, Office of the Commissioner

U.S. Food and Drug Administration

(w) 301-796-8518

(m) (b)(6)

robert.fisher@fda.hhs.gov



From: Branch, Tiffany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B45F1B97B5D648F68CDF5CE4F75A154-TIFFANY.BRA]
Sent: 2/17/2020 2:33:39 PM
To: Fobbs, Linda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a83b8309e0f1497cb8f3cf5aa4ef46f2-Linda.Fobbs]; Yates, Connie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43a5f5be748e40f3a48a41167ea568f7-Connie.Yeld]; Saunders, Shelisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bef2b83443674d87a7e9f87b51654683-Shelisha.Sa]; Biser, Kelley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ab8751f95c34e5a80c9b3b7a7e2c7b3-KBiser]; Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Enoch, Bobby [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=385a224608c04f619542ae28007a2016-Bobby.Enoch]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Green, Jamie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39be8c8f54334a3dbcd557b094db159-Jamie.Green]
Subject: FW: DC-20-04-F: FY 2020 to FY 2024 Coronavirus Resource Estimates [Deadline Extended to COB Wed. Feb. 19th]
Attachments: Copy of FY 20 to FY 24 Coronavirus Outbreak Spending Estimates.xlsx

Good afternoon,

I just want to make sure this is on everyone's radar given the short turnaround [redacted] (b)(5)
[redacted] (b)(5) | We understand that this will just be an estimate given the timeframe.

Best,
Tiffany

From: Tootle, William <William.Tootle@fda.hhs.gov>
Sent: Saturday, February 15, 2020 1:43 PM
To: FDA Office of Budget <FDAOfficeofBudget@fda.hhs.gov>; FDA Budget Formulation Contacts <FDABudgetFormulationContacts@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Green, Jamie <Jamie.Green@fda.hhs.gov>; Enoch, Bobby <Bobby.Enoch@fda.hhs.gov>; Yates, Connie <Connie.Yates@fda.hhs.gov>; Buchanan, Noni <Noni.Buchananp@fda.hhs.gov>; Tan, William <William.Tan@fda.hhs.gov>; Akparewa, Amy <Amy.Akparewa@fda.hhs.gov>; Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Cc: FDA Budget Formulation-OB <FDABudgetFormulationOB@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Matthews-Ockiya, Swynice <Swynice.Matthews-Ockiya@fda.hhs.gov>; Grant, Leonard D <Leonard.Grant@fda.hhs.gov>; FDA Executive Officers <ExecOfficer@fda.hhs.gov>
Subject: RE: DC-20-04-F: FY 2020 to FY 2024 Coronavirus Resource Estimates [Deadline Extended to COB Wed. Feb. 19th]

Hi everyone,

I hate to make another change but we are getting a lot of pressure from HHS and OMB to get our input in on Tuesday. That means we need you to provide your input to us **by noon on Tuesday**.

[redacted] (b)(5)

From: FDA Office of Budget <FDAOfficeofBudget@fda.hhs.gov>

Date: February 14, 2020 at 10:41:02 AM EST

To: FDA Budget Formulation Contacts <FDABudgetFormulationContacts@fda.hhs.gov>, Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>, Green, Jamie <Jamie.Green@fda.hhs.gov>, Enoch, Bobby <Bobby.Enoch@fda.hhs.gov>, Yates, Connie <Connie.Yates@fda.hhs.gov>, Buchanan, Noni <Noni.Buchanan@fda.hhs.gov>, Tan, William <William.Tan@fda.hhs.gov>, Akparewa, Amy <Amy.Akparewa@fda.hhs.gov>, Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>

Cc: FDA Budget Formulation-OB <FDABudgetFormulationOB@fda.hhs.gov>, Tootle, William <William.Tootle@fda.hhs.gov>, Wong, Eric <Eric.Wong@fda.hhs.gov>, Matthews-Ockiya, Swynice <Swynice.Matthews-Ockiya@fda.hhs.gov>, Grant, Leonard D <Leonard.Grant@fda.hhs.gov>, FDA Executive Officers <ExecOfficer@fda.hhs.gov>

Subject: RE: DC-20-04-F: FY 2020 to FY 2024 Coronavirus Resource Estimates [Deadline Extended to COB Wed. Feb. 19th]

Hello Everyone,

We wanted to let everyone know that we received feedback from the centers that the deadline of noon next Tuesday, Feb. 18th, was too aggressive given some staff are out today and also given the holiday weekend. As a result, OB is extending the deadline for the centers and offices to provide their FY 2020 to FY 2024 coronavirus resource estimates via the spreadsheet link below to **COB next Wednesday, Feb. 19th**, based on feedback we received from the centers. The deadline has also been adjusted in both the "Due Dates" and "Background" sections of the data call below. In addition, a minor correction to a column reference has also been made below in red to step 1 under "Spreadsheet Instructions". Thanks.

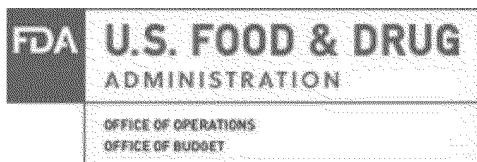
From: FDA Office of Budget <FDAOfficeofBudget@fda.hhs.gov>

Sent: Thursday, February 13, 2020 4:30 PM

To: FDA Budget Formulation Contacts <FDABudgetFormulationContacts@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Green, Jamie <Jamie.Green@fda.hhs.gov>; Enoch, Bobby <Bobby.Enoch@fda.hhs.gov>; Yates, Connie <Connie.Yates@fda.hhs.gov>; Buchanan, Noni <Noni.Buchanan@fda.hhs.gov>; Tan, William <William.Tan@fda.hhs.gov>; Akparewa, Amy <Amy.Akparewa@fda.hhs.gov>; Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>

Cc: FDA Budget Formulation-OB <FDABudgetFormulationOB@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Matthews-Ockiya, Swynice <Swynice.Matthews-Ockiya@fda.hhs.gov>; Grant, Leonard D <Leonard.Grant@fda.hhs.gov>; FDA Executive Officers <ExecOfficer@fda.hhs.gov>

Subject: DC-20-04-F: FY 2020 to FY 2024 Coronavirus Resource Estimates



(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/17/2020 7:01:49 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeb7f3d-Heather.Jan]
CC: Caliguri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: CDC 2019-nCoV Test Update

Yes per yesterday's discussion – thank you.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 7:01 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Yes, I concur with holding off as recommended

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 17, 2020 at 6:58:22 PM EST
To: Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Is the rest of the group good with holding off?

Sent from my iPhone

On Feb 17, 2020, at 6:53 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

Thank you. We will work with Frank in the morning to look for opportunities early next week. Would you like to update the commissioner? Or I can send him a note and cc: this group. Just let me know. Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 17, 2020 6:44 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

If you are recommending pushing, I am fine with that. Sounds like we won't have this wrapped up with CDC either.

Sent from my iPhone

On Feb 17, 2020, at 6:36 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

Replying to this group-

(b)(5)

(b)(5)

(b)(5) I think we could look at early next week as an alternative, but defer to the group. Thank you!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 17, 2020 5:58 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Taking Jeff off. I don't have a noon appearing on my calendar – just fyi.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Monday, February 17, 2020 4:51 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

We actually moved it to the daily noon, which we did not have today because of the holiday but I can re-up for this small group.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 17, 2020 4:36 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Taking Dr. Hahn off – the 5:45 appears as cancelled on calendars. Are we still touching base then in addition to the 5:15?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Monday, February 17, 2020 4:35 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Can do then or we also have the comms call at 5:45. LMK your preference.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 17, 2020 3:41 PM

To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>;

Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

We have a 5:15 call that also includes some CDER colleagues for a check in (thanks Denise), do you want this group to touch base before then or cover during 5:15? Happy to do whatever works best for others.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>

Sent: Monday, February 17, 2020 3:39 PM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff. I can be available.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Date: February 17, 2020 at 3:37:49 PM EST

To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>

Sent: Monday, February 17, 2020 2:04 PM

To: Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <maeanam@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>

Subject: Dx development status and RNA prioritization

Dear Dx WG members,

Thanks to all who participated in the call on Friday. I know that everyone is swamped.

A couple of follow up items:

(b)(5)

(b)(5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA

202-205-8238

Cell: (b)(6)

From: Shuren, Jeff

Sent: Sunday, February 16, 2020 11:05 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>

Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review.

(b)(5)

(b)(5)

Jeff

Internal confidential

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/17/2020 7:07:53 PM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcbbeee5ffeb7f3d-Heather.Jan]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: CDC 2019-nCoV Test Update

I think our mails crossed, will continue to hold.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 7:01 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Yes, I concur with holding off as recommended

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 17, 2020 at 6:58:22 PM EST
To: Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Is the rest of the group good with holding off?

Sent from my iPhone

On Feb 17, 2020, at 6:53 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

Thank you. We will work with Frank in the morning to look for opportunities early next week. Would you like to update the commissioner? Or I can send him a note and cc: this group. Just let me know. Thanks!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 17, 2020 6:44 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

If you are recommending pushing, I am fine with that. Sounds like we won't have this wrapped up with CDC either.

Sent from my iPhone

On Feb 17, 2020, at 6:36 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

Replying to this group-

(b)(5)

(b)(5)

(b)(5)

I think we could look at early next week as an

alternative, but defer to the group. Thank you!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 17, 2020 5:58 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Taking Jeff off. I don't have a noon appearing on my calendar – just fyi.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Monday, February 17, 2020 4:51 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

We actually moved it to the daily noon, which we did not have today because of the holiday but I can re-up for this small group.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 17, 2020 4:36 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Taking Dr. Hahn off – the 5:45 appears as cancelled on calendars. Are we still touching base then in addition to the 5:15?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Monday, February 17, 2020 4:35 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Can do then or we also have the comms call at 5:45. LMK your preference.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Monday, February 17, 2020 3:41 PM

To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>;

Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

We have a 5:15 call that also includes some CDER colleagues for a check in (thanks Denise), do you want this group to touch base before then or cover during 5:15? Happy to do whatever works best for others.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>

Sent: Monday, February 17, 2020 3:39 PM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff. I can be available.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>

Date: February 17, 2020 at 3:37:49 PM EST

To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>

Sent: Monday, February 17, 2020 2:04 PM

To: Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <maeananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>

Subject: Dx development status and RNA prioritization

Dear Dx WG members,

Thanks to all who participated in the call on Friday. I know that everyone is swamped.

A couple of follow up items:

(b)(5)

(b)(5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA

202-205-8238

Cell: (b)(6)

From: Shuren, Jeff

Sent: Sunday, February 16, 2020 11:05 PM

To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>

Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review

(b)(5)

(b)(5)

Jeff

Internal confidential

Sent: 2/17/2020 7:48:23 PM
To: Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffe7f3d-Heather.Jan]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cdf5ce4f75a154-Tiffany.Bra]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Barber, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a326d10d4c5483f843dbb9d59bf1e5d-Daniel.Barb]
Subject: RE: For Clearance Draft InsideFDA FAQs for FDA employees, from Occupational Health

Reviewed and should update with information regarding

From: Tse, Tania <Tania.Tse@fda.hhs.gov>
Sent: Monday, February 17, 2020 6:54 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: Re: For Clearance Draft InsideFDA FAQs for FDA employees, from Occupational Health

Good evening,

Angel and I reviewed and had a chance to discuss this evening. We don't have additional comments. The responses seem reasonable and in keeping with known information.

(b)(5)

(b)(5)

Thanks - Tania

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 14, 2020 at 5:27:25 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather

<Heather.Janik@fda.hhs.gov>, Tse, Tania <Tania.Tse@fda.hhs.gov>, Hebert, Angelique A.
<Angelique.Hebert@fda.hhs.gov>

Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>, Finnen, April
<April.Finnen@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Barber, Daniel <Daniel.Barber@fda.hhs.gov>

Subject: For Clearance Draft InsideFDA FAQs for FDA employees, from Occupational Health

For leadership review – particularly OO. Please provide feedback ASAP. TY

2. **INTERNAL – New InsideFDA FAQs page for FDA employees, from Occupational Health** (latest below – ready to post today, if cleared – these are based on actual questions we are receiving from employees, mostly based on CDC website and FDA travel info, which is already posted)

Draft InsideFDA FAQs for FDA employees, from Occupational Health

(b)(5)

(b)(5)

Additional questions? Contact [FDA Occupational Health Services](#) at 240-402-9177.

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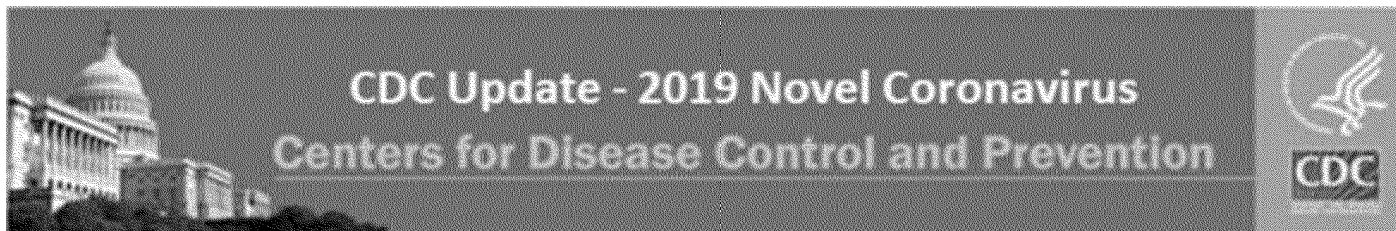
From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
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Subject: Tues/Thursday hill calls
Location: WO1-3771
Start: 2/18/2020 1:00:00 PM
End: 2/18/2020 2:00:00 PM
Show Time As: Tentative
Recurrence: Weekly
every Tuesday and Thursday from 1:00 PM to 2:00 PM
Required Attendees: Denise Hinton; Shirley, Mayo; Black, Jennifer; Aguilar, Paul; Tantillo, Andrew; Pennington, Caitlin

Hi Denise,

I'm still trying to get confirmation regarding this weekly Tues/Thursday 1pm all hill briefings from the Dept. The format tomorrow looks like it will be the same as the last four we did. (b)(5) We'll bring TP's and can come to your office if that sounds good.

Thank you,

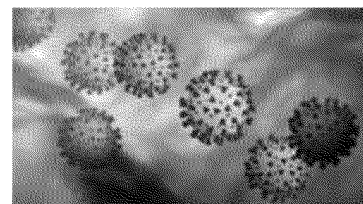
Prakash



Friday, February 14, 2020

Upcoming Briefings/Events:

- Interagency Telebriefing for Hill Staff on COVID-19, February 18, 1:00 PM ET: [RSVP here](#)



Situation Update:

There have been 15 cases of COVID-19 confirmed in the United States, including two cases of transmission to people who had not recently been to China. Two U.S. cases have been identified since Wednesday.

Right now, this virus is not spreading in the community in the United States and the vast majority of Americans have a low risk of exposure. CDC and the US Government have acted to detect and minimize introduction of the virus into the United States. Our scientists and public health experts are learning more about the virus using the data we have from China and the cases we have here.

New since Wednesday:

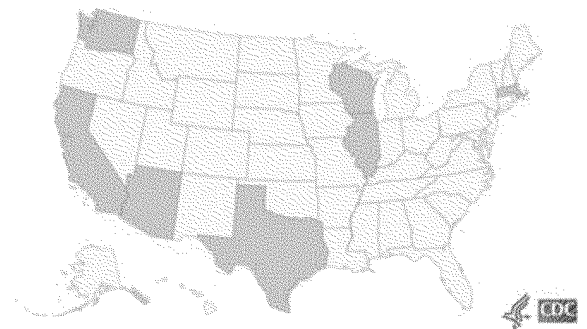
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People Under Investigation (PUI) in the United States since January 21, as of 7:00 PM February 13, 2020: **443**

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- Negative test results: **347**
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⁵Includes specimens received & awaiting testing, as well as specimens en route to CDC



States & territories with PUI: **42**

International Stats:

- Confirmed Cases Globally: **46,997**, as of Feb. 13
- Number of Global Locations with Confirmed Cases: **25** ([view locations with confirmed cases here](#))
- Countries with confirmed person-to-person transmission outside of China: **Thailand, Japan, Singapore, South Korea, Malaysia, Germany, United Kingdom, France, Spain, United Arab Emirates, and the U.S.**

Other Helpful Information for Constituents:

Here are helpful links to information for your constituents about coronavirus, including important steps they can take to prevent the spread of the disease:

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- [CDC Laboratory Test Kits](#)
- [2019-nCoV Infection Control Guidance](#)
- [Frequently Asked Questions and Answers](#)

For questions about CDC's response to COVID-19, please contact the CDC Washington Office at

CDCWNCovResponse@cdc.gov



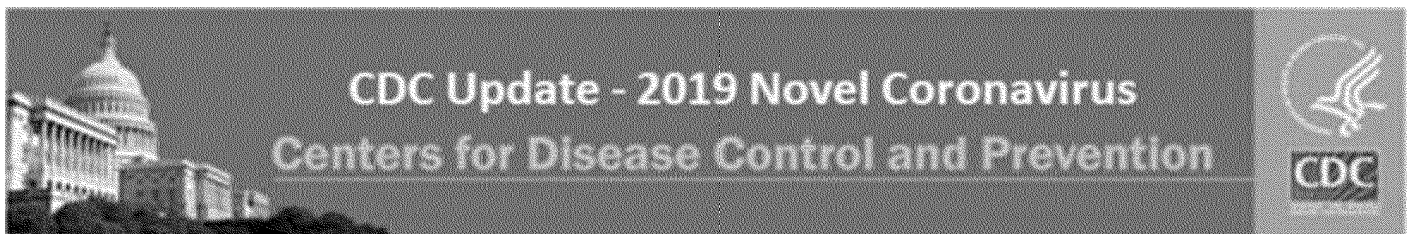
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Subject: Tues/Thursday hill calls
Attachments: Untitled Attachment
Location: WO1-3771
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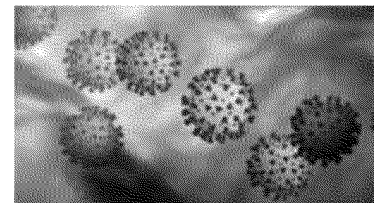
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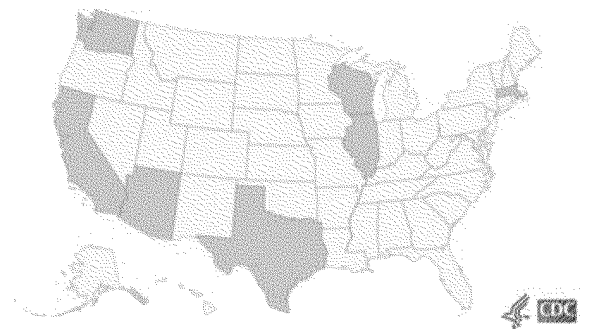
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From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/17/2020 9:08:42 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]
CC: Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]

Subject: Canceled: Canceled: Tues/Thursday hill calls

Attachments: Untitled Attachment

Location: WO1-3771

Start: 2/18/2020 1:00:00 PM

End: 2/18/2020 2:00:00 PM

Show Time As: Free

Importance: High

Recurrence: Weekly
every Tuesday and Thursday from 1:00 PM to 2:00 PM

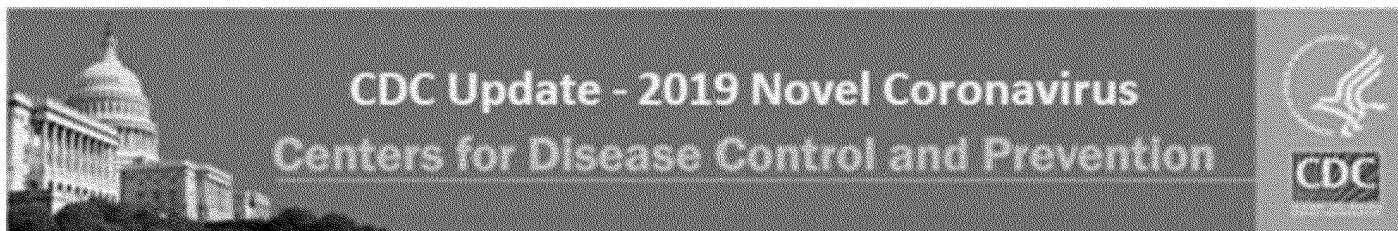
Required Attendees: Hinton, Denise; Shirley, Mayo; Black, Jennifer; Aguilar, Paul; Tantillo, Andrew; Pennington, Caitlin; Raghuwanshi, Rakesh; Price, William

Hi Denise,

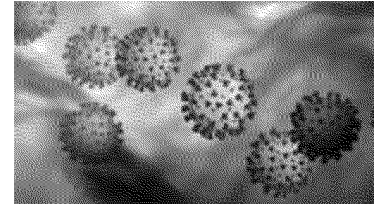
I'm still trying to get confirmation regarding this weekly Tues/Thursday 1pm all hill briefings from the Dept. The format tomorrow looks like it will be the same as the last four we did; (b)(5) We'll bring TP's and can come to your office if that sounds good.

Thank you,

Prakash



Friday, February 14, 2020



Upcoming Briefings/Events:

- Interagency Telebriefing for Hill Staff on COVID-19, **February 18, 1:00 PM ET**: [RSVP here](#)

Situation Update:

There have been 15 cases of COVID-19 confirmed in the United States, including two cases of transmission to people who had not recently been to China. Two U.S. cases have been identified since Wednesday.

Right now, this virus is not spreading in the community in the United States and the vast majority of Americans have a low risk of exposure. CDC and the US Government have acted to detect and minimize introduction of the virus into the United States. Our scientists and public health experts are learning more about the virus using the data we have from China and the cases we have here.

New since Wednesday:

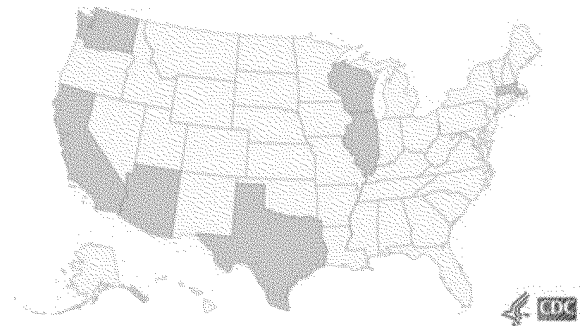
- The 14th and 15th U.S. cases of COVID-19 were confirmed by CDC on Wednesday and Thursday at Marine Corps Air Station Miramar (California) and Lackland Air Force Base (Texas), respectively. The case identified at Lackland marks the first case in Texas, and brings the number of U.S. states with confirmed cases to seven.
- There will be a Two-Part Webinar Series on Legal Preparedness for COVID-19, beginning next week on **February 18, 1:00 PM ET**: [RSVP here](#).
- CDC Developed Several New Fact Sheets:
 - **What You Need to Know**, English, Simplified Chinese, Spanish
 - **What To Do If You Are Sick**, English, Simplified Chinese, Spanish
 - **What the Public Should Do**, English
 - **Stop the Spread of Germs**, English, Simplified Chinese, Spanish
- Find the CDC Digital Press Kit on COVID-19, including links to the latest media telebriefings [here](#).

U.S. Stats

People Under Investigation (PUI) in the United States since January 21, as of 7:00 PM February 13, 2020: **443**

- Positive test results: **15**
- Negative test results: **347**
- Test results pending[§]: **81**

[§]Includes specimens received & awaiting testing, as well as specimens en route to CDC



States & territories with PUI: **42**

International Stats:

- Confirmed Cases Globally: **46,997**, as of Feb. 13
- Number of Global Locations with Confirmed Cases: **25** ([view locations with confirmed cases here](#))
- Countries with confirmed person-to-person transmission outside of China: **Thailand, Japan, Singapore, South Korea, Malaysia, Germany, United Kingdom, France, Spain, United Arab Emirates, and the U.S.**

Other Helpful Information for Constituents:

Here are helpful links to information for your constituents about coronavirus, including important steps they can take to prevent the spread of the disease:

- [Guidance on Prevention and Control](#)
- [Guidance for Travelers](#)

- [Guidance for Ships](#)
- [Transmission](#)
- [Information for Health Care Providers](#)
- [Symptoms & Complications](#)
- [CDC Laboratory Test Kits](#)
- [2019-nCoV Infection Control Guidance](#)
- [Frequently Asked Questions and Answers](#)

For questions about CDC's response to COVID-19, please contact the CDC Washington Office at CDCWNCovResponse@cdc.gov.



From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/18/2020 10:23:30 AM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Patel, Paras M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f5e608bc5f24805a25560be083e1fc8-PATELP]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]; Ngan, Kelly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f7a30838c8bc49428cbbe4959ae8ed6c-NGANK]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfd46-Dinesh.Kuma]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056accc4bc98fdb07bb0548dc86-Paul.Aguila]; 2019-nCoV FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Romano, Lisa M. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9653957f210f4febb1c12c64207346d4-LROMANO]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Mair, Michael

CC: [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai] Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Arsenault, Sam [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f4304f5e82a4bb88d9210e1aa7ecc5b-Samuel.Arse]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]

Subject: prep HELP briefing - COVID 19 Supply chain

Attachments: 2.18.20 SUPPLY CHAIN Talking Points Member meeting for Denise.docx; nCoR 2-18-20 General Talking Points and QnA .docx; 2.18.20 Senate HELP Bipar QnA.docx

Location: WO32 - 1367 (EOC conference room)

Start: 2/18/2020 10:30:00 AM

End: 2/18/2020 11:00:00 AM

Show Time As: Busy

Required Attendees: Hinton, Denise; McSeveney, Megan; Sadove, Elizabeth; Courtney, Brooke; Jensen, Valerie E; Patel, Paras M; Roberts, Rosemary; Ngan, Kelly; Rouse, David; Tomasello, Jennifer; Agler, Heather L; Kumar, Dinesh; Beers, Donald; Rogers, Michael; Shirley, Mayo; Pennington, Caitlin; Gross, Karas; Black, Jennifer; Schipper, Jodi; Tantillo, Andrew; Aguilar, Paul; 2019-nCoV FDA IMG Planning; Abram, Anna; Anderson, Erika; Romano, Lisa M.; Cho, David S (CBER); Mair, Michael

Hello,

We made minor tweaks to the attached documents, and will talk about these and the run of show in a few minutes. We'll bring copies.

Thanks,
Prakash

- The attached TP's may change a bit
- <http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx>
- Includes draft responses to questions, which SME's will convey verbally

Includes QA from ASPR

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Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Arsenault, Sam
[/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: 1`prep HELP briefing - COVID 19 Supply chain
Attachments: 2.18.20 SUPPLY CHAIN Talking Points Member meeting for Denise.docx; nCoR 2-18-20 General Talking Points and QnA .docx; 2.18.20 Senate HELP Bipar QnA.docx
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Sent: 2/18/2020 3:13:50 PM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]
Subject: Read FYSA: BARDA Coronavirus support
Attachments: 2019-nCoV Diagnostics Landscape 2-17-20 v2.pptx

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 10:06 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: RE: BARDA Coronavirus support

Here is a powerpoint to go along with the timeline document.

Best,
Tim

Timothy T. Stenzel, MD, PhD
*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality*

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

Jennifer Campbell
Administrative Assistant

OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

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Sent: Tuesday, February 18, 2020 10:04 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: RE: BARDA Coronavirus support

Thanks Jeff,

The BARDA plan that is supported by OHT7 is attached. They are not seeking financial support but just support for the attached plan as they are (b)(5)

(b)(5)

Best,

Tim

Timothy T. Stenzel, MD, PhD

Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
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Administrative Assistant

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Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
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Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 10:01 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: Re: BARDA Coronavirus support

What support are they seeking from FDA?

Adding Keagan, Anna, and Denise for awareness.

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: February 18, 2020 at 9:08:13 AM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: BARDA Coronavirus support

Hi Jeff,

Rosemary Humes from BARDA has reached out to Uwe and me and asked for support in their plans to: (b)(5)

(b)(5)

I am in the process of generating text language for this support to send you this morning. She is wondering if we can get FDA support up through the Commissioner and on up to the Department as needed. She is asking for CDC support too and if there is a CDC call today, I am going to jump on that. She asked me if CMS and/or CLIA could also support but I was unsure of who and how strong their knowledge would be and if they could add something.

Thanks!

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality*

Center for Devices and Radiological Health

U.S. Food and Drug Administration

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<https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E>

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/18/2020 4:53:16 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]
Subject: sitrep
Attachments: 18_2019-nCoV Outbreak_FDA SITREP_18 February 2020.docx

Thx – sorry late

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/18/2020 4:55:25 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]
Subject: RE: sitrep
Attachments: 18_2019-nCoV Outbreak_FDA SITREP_18 February 2020.docx
Importance: High

Use this version – just a couple of copy edits.

From: Mair, Michael
Sent: Tuesday, February 18, 2020 4:53 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Measer, Gregory <Gregory.Measer@fda.hhs.gov>
Subject: sitrep

Thx – sorry late

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/18/2020 8:03:41 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebee5ffeeb7f3d-Heather.Jan]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: CDC 2019-nCoV Test Update

Thanks Laura.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 8:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Per KL's timing, we will set for after AEG and sync as needed during the day. Invite to follow.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:56 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

My preference is to meet immediately following the evening AEG, 0830 or after the Commissioner's 0900 call but will go with the majority if the vote for mid-day meetings prevail. I will adjust my calendar accordingly.

Thanks,

Denise

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 6:44 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Days are really tough for me. I could do mornings or early evenings.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 6:37 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

That w

That was the intent of pulling to noon to cover forward leaning and clearing pending. Could you all identify a time mid day. Throwing out 1pm as a new starting point -please lmk avail or other preferences.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Date: February 18, 2020 at 6:28:41 PM EST

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

8:30 is fine, but if it is morning of are we already a step behind?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Date: February 18, 2020 at 6:24:18 PM EST

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

I am thinking right after the AEG normally, but it could be we have to connect with SH right after like we did today. Open to peoples thoughts? Before 9am?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Tuesday, February 18, 2020 6:22 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

We moved our time up to noon and it is not working for Anna, KL or Denise. So, please lmk when the best brief out time is for you all and we will move.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Tuesday, February 18, 2020 5:24 PM

To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Subject: RE: CDC 2019-nCoV Test Update

Minus Jeff, plus Erika

I'm still confused on how we are doing these check ins now as we had discussed doing in the am or pm to drive messaging and I'm not on the invite?? Syncing on the messaging is very important not just for comms, but the other Hill and HHS engagements/considerations. For example: (b)(5) this week. Thanks.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:51 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

We actually moved it to the daily noon, which we did not have today because of the holiday but I can re-up for this small group.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:36 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Taking Dr. Hahn off – the 5:45 appears as cancelled on calendars. Are we still touching base then in addition to the 5:15?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:35 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Can do then or we also have the comms call at 5:45. LMK your preference.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 3:41 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

We have a 5:15 call that also includes some CDER colleagues for a check in (thanks Denise), do you want this group to touch base before then or cover during 5:15? Happy to do whatever works best for others.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 17, 2020 3:39 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff. I can be available.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: February 17, 2020 at 3:37:49 PM EST
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

I have an update. It might be better to discuss by phone if folks are available.

Also, below I'm sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemarv.Humes@hhs.gov>
Sent: Monday, February 17, 2020 2:04 PM
To: Kuhnert-Tallman, Wendi L (CDC) <wdk1@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA) <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
Subject: Dx development status and RNA prioritization

Dear Dx WG members,
Thanks to all who participated in the call on Friday. I know that everyone is swamped.
A couple of follow up items:

(b)(5)

(b)(5)

Rosemary Humes MS, MT(ASCP) SM
HHS/ASPR/BARDA
202-205-8238
Cell (b)(6)

From: Shuren, Jeff
Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review (b)(5)

(b)(5)

Jeff

Internal confidential

From: Walsh, Sandy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C61503C4E7884FC28B9EF6CB8F2514EC-SANDY.WALSH]
Sent: 2/19/2020 12:47:48 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC
Attachments: 20200219_Readout FIB SMH ASPR SOC - OCC cleared.docx

Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

(b)(5)

(b)(5)

(b)(5)

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov



From: Branch, Tiffany [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B45F1B97B5D648F68CDF5CE4F75A154-TIFFANY.BRA]
Sent: 2/19/2020 2:04:32 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Hebert, Angeliq ue A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angeliq ue.H]
Subject: FW: FDA 2019-nCOV SITREP - 18 Feb 2020
Attachments: 18_2019-nCoV Outbreak_FDA SITREP_18 February 2020.docx

Good afternoon,

To ensure we are aligned with the Centers as we move forward, I would like to forward the SITREP document to the Center EOs on a daily basis following the Executive Meeting at 5:15. Since we are no longer having daily EO calls, this will ensure their Directors have already reviewed the information, but provide EOs with some context for the discussions they are having with their leadership. If you have no objections, I will begin the process today.

Best,
Tiffany

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 6:36 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angeliq ue A. <Angeliq ue.Hebert@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Cc: Measer, Gregory <Gregory.Measer@fda.hhs.gov>
Subject: FDA 2019-nCOV SITREP - 18 Feb 2020

Hi,

Attached for your situational awareness is the 18 February FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support. -Michael

From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/19/2020 2:44:06 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Just seeing this as I have been in meetings with the Commissioner. Can try and turn around by 3:30 (Sec mtg)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 2:39 PM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Denise Anna and KL
Let us know if 3pm is a reasonable turnout or what will work for you. TY.
Laura

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 12:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
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Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

(b)(5)

(b)(5)

(b)(5)

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov



From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/19/2020 2:47:57 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32ceb4b4f80b302c50cf31c8524-Stephanie.C]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Some suggested changes:

(b)(5)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 2:39 PM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
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Laura

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Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah

<Sarah.Lynch@fda.hhs.gov>

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U.S. Food and Drug Administration
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From: Abram, Anna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/19/2020 2:57:03 PM
To: Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0fed46c7b1bfcddd41f240d7-Megan.McSev]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC
Attachments: 20200219_Readout FIB SMH ASPR SOC - OCCAA cleared.docx

Suggested edits in the attached

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 12:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
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Sandy Walsh

Acting Director

Office of Editorial and Creative Services

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301-796-4669

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/19/2020 3:08:48 PM
To: Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC
Attachments: 20200219_Readout FIB SMH ASPR SOC - OCCAA cleared.docx

Thanks – I agree with suggested edits.

Denise

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 3:01 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Thanks all. Will make the edits and get this into HW for tonight.

Heidi, re: the photo, we are checking to see what else is available.

Sandy Walsh
Acting Director
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Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov



From: Abram, Anna <Anna.Abram@fda.hhs.gov>

Sent: Wednesday, February 19, 2020 2:57 PM

To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

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Sandy.Walsh@fda.hhs.gov



From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/19/2020 4:42:40 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]
Subject: today's SITREP
Attachments: 19_2019-nCoV Outbreak_FDA SITREP_19 February 2020.docx

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/19/2020 5:30:04 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6);
(b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6);
(b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6);
(b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHC (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6);
(b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6);
Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6);
(b)(6); Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Hudson, Renee R. EOP/WHO (b)(6);
(b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6);
(b)(6); Lin, Merry S. EOP/WHO [Merry.S.Lin@who.eop.gov]; McKenna, Michael A. EOP/WHQ (b)(6); Merkel, Theo W. EOP/WHO (b)(6);
(b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William [WaltersWA2@state.gov]; Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcedd4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot@hq.dhs.gov; amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron [aaron.firoved@HQ.DHS.GOV]; Limage, Julia [julia.limage@hq.dhs.gov]; Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC [Elijah.J.Waterman@nsc.eop.gov]; Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0ccb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M [TobertGM@state.gov]; Scovitch, Joseph R [ScovitchJR@state.gov]; Costello, Kelly E [CostelloKE@state.gov]; DL NSC IO (b)(6); DL NSC Asia [DL.Asia@whmo.mil]; DL NSC Press (b)(6); DL NSC Resilience [DL.Resilience@whmo.mil]; DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS [DL.BATS@whmo.mil]; Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu [GulatiN1@state.gov]; Liebschutz, Jennifer E. EOP/OMB (b)(6); quharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

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(b)(6); Frater, Eric M [FraterEM@state.gov]; Christ, Katelyn E. EOP/NSC
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.J.andc.ou=Ryan P.
EOP/NSC (b)(6); Rault, Nick M. EOP/NSC (b)(6); Hanna, Cory M.
EOP/NSC (b)(6); Burton, Nicholas S. EOP/OMB [Nicholas_S_Burton@omb.eop.gov]; Garufi,
Marc A. EOP/OMB (b)(6); Mroz, Sara K. EOP/NSC (b)(6); Troye, Olivia
EOP/NSC [Olivia.Troye@nsc.eop.gov]; Carlson, Eric J [CarlsonEJ@state.gov]; McGowan, Robert K (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J.
EOP/NSC (b)(6); Cartin, Josh M. EOP/NSC (b)(6); Kanapathy, Ivan
J. EOP/NSC (b)(6); Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6); Bakewell, Richard A [BakewellRA@state.gov]; Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
EOP/NSC (b)(6); Brett Armstrong - D1R [brett.armstrong@gsa.gov];
paul.detitta@gsa.gov; Marwaha, Brianna C [MarwahaBC@state.gov]; Carstens, Virgil W [CarstensVW@state.gov];
Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdfac04264888a-HHS-David.H]; McMillin, Virginia D.
EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Sugarman,
AJ J. EOP/WHO (b)(6); Planning, David M. EOP/WHO (b)(6);
Feddersen, Brett [FAA] [Brett.Feddersen@faa.gov]; Padget, Larry G [PadgetLG@state.gov]; Greene Richard S.
[GH/IDN] [USAID] [rgreene@usaid.gov] greene@usaid.gov; Baehr, James S. EOP/WHO
(b)(6); Magrino, Christopher [Christopher.Magrino@HQ.DHS.GOV];
debbie.w.seguin@cbp.dhs.gov; william.ferrara@cbp.dhs.gov; Tobin, Elizabeth D. EOP/NSC
(b)(6); Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J
[MartinGJ@state.gov]; Music, Chris G. EOP/OMB (b)(6); Ali, Nausher [AliSN@state.gov];
Burris, Meghan K. EOP/WHO (b)(6); Henning, Alexa A. EOP/WHO
(b)(6); Daravi, Roma S. EOP/WHO (b)(6); Horstman, John
H. EOP/WHO (b)(6); MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
(b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Martin, Michael
E. EOP/NSC (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC
(b)(6); Gray, Alexander B. EOP/NSC (b)(6); Rubini, Jeffrey H.
EOP/NSC (b)(6); Ulyot, John L. EOP/NSC (b)(6); Stufft, Julie M.
EOP/NSC (b)(6); Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6); Davis, May M. EOP/WHO (b)(6); Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6); Thallam, Satya
P. EOP/OMB (b)(6); Allen, Ronald G. EOP/NSC (b)(6); Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB
(b)(6); Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6); Mesquita, Mario M [MesquitaMM@state.gov]; Millard, Christopher
A. Cbti CTR OSD OUSD POLICY (USA) (b)(6); DL Chief of Staff Office
(b)(6); victocg@ucia.gov; danielz@ucia.gov; Ash, Deborah J. EOP/NSC
(b)(6); Reilly, Tom M. EOP/OMB (b)(6); Havranek, John

[John.Havranek@HQ.DHS.GOV]; Dumm, Christopher M [DummCM@state.gov]; FORET, VERNON T [VERNON.T.FORET@CBP.DHS.GOV]; Ellis, Michael J. EOP/WHO; (b)(6); Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC; (b)(6); JACKSTA, LINDA L. [LINDA.L.JACKSTA@chc.dhs.gov]; Parra, Yolanda A [ParraYA@state.gov]; Carter, Hillary H. EOP/NSC; (b)(6); Galkowski, James J. EOP/WHO; (b)(6); Tokumasu de Silva, Miriam E [TokumasuME2@state.gov]; Doyle, Emma K. EOP/WHO; (b)(6); Lason, Adam J. EOP/NSC; (b)(6); McPheeME@state.gov; Carson, Tracy L (Geneva) [CarsonTL@state.gov]; Bibo, David [David.Bibo@fema.dhs.gov]; Dorko, Jeffrey [Jeffrey.Dorko@fema.dhs.gov]; Hughes, William C. (ODAG) [William.C.Hughes@usdoj.gov]; Hamel, Michael A (Mike) CTR OSD OUSD POLICY (USA) (b)(6); Syptak-Ramnath, Stephanie F [syptak-ramnathsf@state.gov]; david.short@dot.gov; Isenberg, Daniel T CTR OSD OUSD POLICY (USA) [daniel.t.isenberg.ctr@mail.mil]; Okediji, Adedeji E (Beijing) [OkedijiAE@state.gov]; De La Riva, Etienne EOP/NSC; (b)(6); Morgan, Jameson A. EOP/NSC; (b)(6); Smith, Jason S. EOP/NSC; (b)(6); Durie, Troy M. EOP/CEA; (b)(6); Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]

Subject: SARS-CoV-2 (b)(5)
Attachments: Agenda 20 Feb FINAL.docx
Location: SVTC and Room 381 for EOP Staff

Start: 2/20/2020 10:00:00 AM
End: 2/20/2020 11:00:00 AM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

Please accept this invite for a virtual (b)(5) tomorrow morning from 1000-1100. There are no rooms available, so EOP staff are welcome to join in room 381 in SAP Ruggiero's office.

Please find the agenda attached.

All the best,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/19/2020 5:30:04 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Proegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

[kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6) Tully, Ryan M. EOP/NSC
(b)(6) Frater, Eric M (b)(6) Christ, Katelyn E. EOP/NSC
(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Troye, Olivia
EOP/NSC (b)(6) Carlson, Eric J (b)(6) McGowan, Robert K (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J.
EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A (b)(6) Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov];
paul.detitta@gsa.gov; Marwaha, Brianne C (b)(6) Carstens, Virgil W (b)(6);
Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D.
EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Sugarman,
AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6)
Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6) Greene Richard S.
(GH/HIDN) [USAID] [rgreene@usaid.gov] [rgreene@usaid.gov]; Baehr, James S. EOP/WHO
(b)(6) Magrino, Christopher (b)(6)
debbie.w.seguin (b)(6) william.ferrara (b)(6) Tobin, Elizabeth D. EOP/NSC
(b)(6) Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J
(b)(6) Music, Chris G. EOP/OMB (b)(6) Ali, Nausher (b)(6)
Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO
(b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John
H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
(b)(6) Wilson, John Mark M. EOP/NSC (b)(6) Martin, Michael
E. EOP/NSC (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC
(b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
EOP/NSC (b)(6) Ulyot, John L. EOP/NSC (b)(6) Stufft, Julie M.
EOP/NSC (b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6) Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6) Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya
P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB
[Alyssa_P_Bain@omb.eop.gov]; Schroyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd];
alexandra.doumas@usdoj.gov; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M (b)(6) Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6) DL Chief of Staff Office
(b)(6) Ash, Deborah J. EOP/NSC
(b)(6) Reilly, Tom M. EOP/OMB (b)(6) Havranek, John

(b)(6); Dumm, Christopher M (b)(6) FORET, VERNON T
(b)(6) Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew
(ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC (b)(6) JACKSTA,
LINDA (b)(6) Parra, Yolanda A (b)(6) Carter, Hillary H. EOP/NSC
(b)(6) Galkowski, James J. EOP/WHO (b)(6) Tokumasu de
Silva, Mir iam E (b)(6) Doyle, Emma K. EOP/WHO (b)(6) Lason, Adam
J. EOP/NSC (b)(6) McPheeME (b)(6) Carson, Tracy L (Geneva) (b)(6)
Bibo, David (b)(6) Dorko, Jeffrey (b)(6) Hughes, William C. (ODAG)
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Isenberg, Daniel T CTR OSD OUSD POLICY (USA) (b)(6) Okediji, Adedeji E (Beijing)
(b)(6) De La Riva, Etienne EOP/NSC (b)(6) Morgan, Jameson A.
EOP/NSC (b)(6) Smith, Jason S. EOP/NSC (b)(6); Durie, Troy M.
EOP/CEA (b)(6) Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]

Subject: SARS-CoV-2 (b)(5)
Attachments: Agenda 20 Feb_FINAL.docx
Location: SVTC and Room 381 for EOP Staff

Start: 2/20/2020 10:00:00 AM
End: 2/20/2020 11:00:00 AM
Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

Please accept this invite for a virtual (b)(5) tomorrow morning from 1000-1100. There are no rooms available, so EOP staff are welcome to join in room 381 in SAP Ruggiero's office.

Please find the agenda attached.

All the best,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/19/2020 5:30:04 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHQ (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Foster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO [Alexandra.D.Campana2@who.eop.gov]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William [WaltersWA2@state.gov]; Bonner, Maria K. EOP/WHO [Maria.K.Bonner@who.eop.gov]; Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot@hq.dhs.gov; amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron [aaron.firoved@HQ.DHS.GOV]; Limage, Julia [julia.limage@hq.dhs.gov]; Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC [Elijah.J.Waterman@nsc.eop.gov]; Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Rej]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

[kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6) Tully, Ryan M. EOP/NSC
(b)(6) Frater, Eric M [FraterEM@state.gov]; Christ, Katelyn E. EOP/NSC
(b)(6) Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
EOP/NSC (b)(6) Rault, Nick M. EOP/NSC (b)(6) Hanna, Cory M.
EOP/NSC (b)(6) Burton, Nicholas S. EOP/OMB (b)(6) Garufi,
Marc A. EOP/OMB (b)(6) Mroz, Sara K. EOP/NSC (b)(6) Troye, Olivia
EOP/NSC [Olivia.Troye@nsc.eop.gov]; Carlson, Eric J [CarlsonEJ@state.gov]; McGowan, Robert K [CDC
/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J.
EOP/NSC (b)(6) Cartin, Josh M. EOP/NSC (b)(6) Kanapathy, Ivan
J. EOP/NSC (b)(6) Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative
Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6) Bakewell, Richard A [BakewellRA@state.gov]; Thomas, Gloria D (OS)
/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J.
EOP/NSC (b)(6) Brett Armstrong - D1R [brett.armstrong@gsa.gov];
paul.detitta@gsa.gov; Marwaha, Brianna C [MarwahaBC@state.gov]; Carstens, Virgil W [CarstensVW@state.gov];
Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D.
EOP/WHO (b)(6) Telle, Adam R. EOP/WHO (b)(6) Sugarman,
AJ J. EOP/WHO (b)(6) Planning, David M. EOP/WHO (b)(6)
Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G [PadgetLG@state.gov]; Greene Richard S.
(GH/HIDN) [USAID] [rgreene@usaid.gov] [rgreene@usaid.gov]; Baehr, James S. EOP/WHO
(b)(6) Magrino, Christopher [Christopher.Magrino@HQ.DHS.GOV];
debbie.wseguin@cbp.dhs.gov; william.ferrara@cbp.dhs.gov; Tobin, Elizabeth D. EOP/NSC
(b)(6) Jonas, Seth H. EOP/NSC (b)(6) Martin, Gregory J
[MartinGJ@state.gov]; Music, Chris G. EOP/OMB (b)(6) Ali, Nausher [AliSN@state.gov];
Burris, Meghan K. EOP/WHO (b)(6) Henning, Alexa A. EOP/WHO
(b)(6) Daravi, Roma S. EOP/WHO (b)(6) Horstman, John
H. EOP/WHO (b)(6) MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
[francesca.c.music2.civ@mail.mil]; Wilson, John Mark M. EOP/NSC (b)(6) Martin, Michael
E. EOP/NSC (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC
(b)(6) Gray, Alexander B. EOP/NSC (b)(6) Rubini, Jeffrey H.
EOP/NSC (b)(6) Ulyot, John L. EOP/NSC (b)(6) Stufft, Julie M.
EOP/NSC (b)(6) Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6) Davis, May M. EOP/WHO (b)(6) Lekan, Scott M (ACF)
/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6) Bailey, Drew M. EOP/OMB (b)(6) Thallam, Satya
P. EOP/OMB (b)(6) Allen, Ronald G. EOP/NSC (b)(6) Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB
(b)(6) Schroyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; Hinton, Denise
/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6) Mesquita, Mario M [MesquitaMM@state.gov]; Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) [christopher.a.millard.ctr@mail.mil]; DL Chief of Staff Office
[DLChiefofStaffOffice@WHO.eop.gov]; victocg@ucia.gov; danietz@ucia.gov; Ash, Deborah J. EOP/NSC
(b)(6) Reilly, Tom M. EOP/OMB (b)(6) Havranek, John

[John.Havranek@HQ.DHS.GOV]; Dumm, Christopher M [DummCM@state.gov]; FORET, VERNON T [VERNON.T.FORET@CBP.DHS.GOV]; Ellis, Michael J. EOP/WHO (b)(6); Blue, Matthew (ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC (b)(6); JACKSTA, LINDA L [LINDA.L.JACKSTA@cbp.dhs.gov]; Parra, Yolanda A [ParraYA@state.gov]; Carter, Hillary H. EOP/NSC (b)(6); Galkowski, James J. EOP/WHO (b)(6); Tokumasu de Silva, Miriam E [TokumasuME2@state.gov]; Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam J. EOP/NSC (b)(6); McPheeME@state.gov; Carson, Tracy L (Geneva) [CarsonTL@state.gov]; Bibo, David [David.Bibo@fema.dhs.gov]; Dorko, Jeffrey [Jeffrey.Dorko@fema.dhs.gov]; Hughes, William C. (ODAG) [William.C.Hughes@usdoj.gov]; Hamel, Michael A (Mike) CTR OSD OUSD POLICY (USA) (b)(6); Syptak-Ramnath, Stephanie F [syptak-ramnathsf@state.gov]; david.short@dot.gov; Isenberg, Daniel T CTR OSD OUSD POLICY (USA) (b)(6); Okediji, Adedeji E (Beijing) [OkedijiAE@state.gov]; De La Riva, Etienne EOP/NSC (b)(6); Morgan, Jameson A. EOP/NSC (b)(6); Smith, Jason S. EOP/NSC (b)(6); Durie, Troy M. EOP/CEA (b)(6); Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Eisenberg, John A. EOP/WHO (b)(6); Bai, Sue J. EOP/WHO [Sue.J.Bai@who.eop.gov]

CC: Sappenfield, Christine A [SappenfieldCA@state.gov]; Hennessey, Millicent S. EOP/NSC (b)(6)

Subject: SARS-CoV-2 (b)(5)
Attachments: Agenda 20 Feb_FINAL.docx
Location: SVTC and Room 381 for EOP Staff
Start: 2/20/2020 10:00:00 AM
End: 2/20/2020 11:00:00 AM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

Please accept this invite for a virtual (b)(5) tomorrow morning from 1000-1100. There are no rooms available, so EOP staff are welcome to join in room 381 in SAP Ruggiero's office.

Please find the agenda attached.

All the best,

Phil

From: Hodnette, Jonathan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EEOFF4C9FE6418EA8BF16A891DB85B9-JONATHAN.HO]
Sent: 2/20/2020 9:32:54 AM
To: Agler, Heather L [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=090e915048c74139ab1e0f11e16f05ea-HLA]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Rogers, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62d7370b5f3549728e02139b9792502c-MROGERS2]; Laska, Susan F [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2945f85080e546589ad31434c34663ae-LASKAS]; Jensen, Valerie E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e940a2d8ae47461296d03872f74d9a6a-JENSENV]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Luebke, Yasemin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Od4b7fc0cfed46c7b1bfcd41f240d7-Megan.McSev]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Rouse, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=185bae767862490d88eda44db74a75b3-RouseD]; Kumar, Dinesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=508e6d982bff426cab84531e12cfdd46-Dinesh.Kuma]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: 2019-nCoV FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Measer, Gregory [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e45932a791a6486f906825f5f3a49e85-Gregory.Mea]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mignone, Alfred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Malais, Tanya
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f13699d67e9c491eab11150a04f7fc6c-Tanya.Malai]

Subject: RE: Phone Briefing HSGAC COVID-19

Attachments: 2.20.20 Hill Briefing Opening Remarks.docx; COVID 19 Talking Points_2.19.20_6pm.docx

Hi all,

Thank you for sticking with us as this briefing moved around and came together rather quickly. OMA provided us some updated TPs last night that we have attached and used to make updates to Denise's opening remarks. We will bring copies to the briefing, and we will be there in advance of the briefing should anyone have any questions you'd like to discuss ahead of time.

Best,

Jon

-----Original Appointment-----

From: Hodnette, Jonathan

Sent: Tuesday, February 18, 2020 1:19 PM

To: Hodnette, Jonathan; Agler, Heather L; Hinton, Denise; Rogers, Michael; Laska, Susan F; Jensen, Valerie E; Schipper, Jodi; Andrew Tantillo (Andrew.Tantillo@fda.hhs.gov); Rath, Prakash (FDA); Black, Jennifer; Luebke, Yasemin; Aguilar, Paul; Raghuwanshi, Rakesh; Tomasello, Jennifer; Pennington, Caitlin; Shirley, Mayo; Van Pool, Kendall; BriefingOL@sharepoint.fda.gov; Oxner, Julie (OS); Rybak, Bailey (OS/ASPR/OEA); Pence, Laura (OS); Kehoe, Brian (OS); Honig, Esther (OS); McSeveney, Megan; Sadove, Elizabeth; Rouse, David; Kumar, Dinesh; Cho, David S (CBER); Tierney, Julia

Cc: 2019-nCoV FDA IMG Planning; Measer, Gregory; Courtney, Brooke; Mair, Michael; Mignone, Alfred; Shuy, Bryan (OS/ASPR/IO); Ross, Aftin; Malais, Tanya; Adams, Steven A. (CDC/SNS/DSNS)

Subject: Phone Briefing HSGAC COVID-19

When: Thursday, February 20, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: WO32, Rm 1305 and WebEx

Time confirmed with Committee staff.

This briefing was requested by Senate HSGAC Minority staff (b)(5)

(b)(5) (i.e. RADM Hinton will provide opening remarks and SMEs to provide support for QA).

-- Do not delete or change any of the following text. --

When it's time, join your Webex meeting here.

Meeting number (access code): (b)(6)

Meeting password: (b)(6)

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Global call-in numbers | Toll-free calling restrictions

If you are a host, go [here](#) to view host information.

Need help? Go to <http://help.webex.com>

From: Ross, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AE562EA1D840A3ACA172D0CC23F368-ROSSJ]
Sent: 2/20/2020 9:54:34 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
CC: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Prep for FDA/CDC Visit tomorrow
Attachments: Summary of Pending IVD Proposals 2-20-20 FINAL.doc

Denise,

As background for the meeting tomorrow morning, and as you requested, attached is the document Liz and I prepared. (b)(5)

(b)(5)

(b)(5)

My understanding from Tim Stenzel is that FDA is

(b)(5)

(b)(5)

Thanks,

Jennifer

-----Original Appointment-----

From: Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>

Sent: Wednesday, February 19, 2020 10:05 AM

To: Campbell, Jennifer; Stenzel, Timothy; Hillebrenner, Elizabeth J; Brenner, Sara; Lowe, Toby A; lademarco, Michael (CDC); Ramsey, Melanie R (CDC); Salerno, Reynolds M (CDC); Sen, Oishee (CDC); Burns, Annina (CDC); King, Veronnica (CDC); Howard, Stacy M (CDC); Hinton, Denise; Pillai, Segaran; Scherf, Uwe; Monroe, Stephan S (CDC)

Cc: Gross, Karas; Paulos, Lauren; Flannery, Ellen; Tomasello, Jennifer; Shuren, Jeff; Rubinstein, Wendy; Ross, Jennifer; Sadove, Elizabeth

Subject: FDA/CDC Visit

When: Friday, February 21, 2020 8:45 AM-12:15 PM (UTC-05:00) Eastern Time (US & Canada).

Where: 10903 New Hampshire Ave, Silver Spring MD , White Oak Bldg 66 Room 5425

8:45 - 9 am - Arrive and setup

1. 9-9:30 am - VALID Act and LDTs
2. 9:30-10 am - Sufficiency of CLIA
3. 10-11 am EUA
4. 11 am – 12 pm - Biosafety (including with IVD)

12-12:15 pm – Discuss planning of next meeting

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/20/2020 10:19:05 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]
CC: Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]
Subject: Today's hill briefings - 2/20/20
Attachments: 2.20.20 Hill Briefing Opening Remarks.docx; COVID 19 Talking Points_2.19.20_6pm.docx

Hi Denise,

We've sent a lot of emails and requests in the past couple of days and just wanted to make sure you were comfortable and ok with today's plan.

- **HSGAC briefing – 12PM:** Attached are your opening remarks for the noon briefing. (b)(5)
(b)(5)

understand that you may have to leave early, and we will fill you in if there is any follow up.

- Jon and I will be in the FDA-Track room (32-1305); (b)(5) Please feel free to join us early if you would like to go over anything.
- ASPR will be on the call, and for your awareness the following folks will join:
 - Bryan Shuy, Deputy Assistant Secretary for Preparedness and Response
 - Steven Adams, Director of the Strategic National Stockpile
 - Dr. Laura Wolf, Director of Critical Infrastructure Protection

- **Bicameral hill briefing 1PM:** I will join you in your office for the next briefing. You do not need to give remarks. If questions for FDA come up, we will pull from the TP's on the second attachment.

Please let us know if you have any questions, see you soon.

Thank you,
Prakash

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 10:48:48 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FYI: 2019-nCoV regulatory science gaps NCTR Proposal
Attachments: Azevedo_Coronavirus_Estimates.pdf

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 10:48 AM
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR Proposal

GM All:
Sharing the NCTR Coronavirus Proposal that has been submitted to OBFA. Per a conference call today, this will be discussed with DHHS & OMB as soon as tomorrow.

Thanks,
Charlotte

"A lie doesn't become truth, wrong doesn't become right and evil doesn't become good just because it's accepted by a majority." Booker T. Washington

From: Ashcraft, Charlotte
Sent: Thursday, February 20, 2020 9:46 AM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR

GM All:

(b)(5)

Thanks,

Charlotte

"A lie doesn't become truth, wrong doesn't become right and evil doesn't become good just because it's accepted by a majority." Booker T. Washington

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 9:12 AM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Here you are.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Craft, William
Sent: Wednesday, February 19, 2020 8:20 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov





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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:10 AM
To: Craft, William <William.Craft@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi Doug,

Please do [redacted (b)(5)]

Thank you!

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:06 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

Take a look at these and make sure I have captured everything. [redacted (b)(5)]
[redacted (b)(5)]

[redacted (b)(5)]

Keep in mind that this [redacted (b)(5)]

Thanks for getting these estimates to me.

Feel free to call if you have any questions.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:54 AM
To: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Sorry,

(b)(5)

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:51 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

I didn't see any: (b)(5)

Can you provide me this info asap?

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 2:59 PM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>; Foley, Steven <Steven.Foley@fda.hhs.gov>; Cerniglia, Carl <Carl.Cerniglia@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Thank you

From: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>

Sent: Tuesday, February 18, 2020 8:32 AM

To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>

Cc: Craft, William <William.Craft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

Marli, yes, go ahead and move forward.

Tucker A. Patterson, Ph.D.

Associate Director for Science & Policy

National Center for Toxicological Research



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Sent: Tuesday, February 18, 2020 8:31 AM

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Cc: Craft, William <William.Craft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

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Cc: Craft, William <William.Craft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

GM All:

The data call is due today. If you want to work with Doug Craft to put together an estimate for a project, I'm happy to submit. (b)(5)

(b)(5)

Thanks

Charlotte

From: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>

Sent: Tuesday, February 18, 2020 8:01 AM

To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>

Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

Marli, I am running this by Charlotte to get her opinion. Thanks.

Tucker

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Should we work to put one together for NCTR?

Marli

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
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To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

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<Todd.Myers@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

Thx for your assistance. – m

(b)(5)

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Sent: Wednesday, February 5, 2020 12:14 PM

To: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>

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Subject: 2019-nCoV regulatory science gaps

Takeaways from Monday's meeting on regulatory science gaps:

(b)(5)

(b)(5)

Please let me know if I've omitted anything....

Best,
Robert

Robert W. Fisher, Ph.D.

Senior Advisor for CBRN and Pandemic Influenza

Office of Counterterrorism and Emerging Threats (OCET)

Office of the Chief Scientist, Office of the Commissioner

U.S. Food and Drug Administration

(w)301-796-8518

(r) [REDACTED]

robert.fisher@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 10:57:28 AM
To: Ashcraft, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3defaed236074242aced487d77b09b47-Cmashcraft]; Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Cason, Winona [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3434073fc4cc4b578c59ca60a5da91f8-Winona.Caso]
Subject: RE: 2019-nCoV regulatory science gaps NCTR Proposal

Thank you, Charlotte.

Best,

Denise

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 10:48 AM
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR Proposal

GM All:

Sharing the NCTR Coronavirus Proposal that has been submitted to OBFA. Per a conference call today, this will be discussed with DHHS & OMB as soon as tomorrow.

Thanks,
Charlotte

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From: Ashcraft, Charlotte
Sent: Thursday, February 20, 2020 9:46 AM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR

GM All:

(b)(5)

(b)(5)

Thanks,
Charlotte

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From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 9:12 AM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Here you are.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Craft, William
Sent: Wednesday, February 19, 2020 8:20 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

Thanks,

William Douglas Craft
Management Analyst

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National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:10 AM
To: Craft, William <William.Craft@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi Doug,

Please do: [redacted] (b)(5)

Thank you!

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:06 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

Take a look at these and make sure I have captured everything. [redacted] (b)(5)

[redacted] (b)(5)

[redacted] (b)(5)

Keep in mind that this [redacted] (b)(5)

Thanks for getting these estimates to me.

Feel free to call if you have any questions.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:54 AM
To: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Sorry,

(b)(5)

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:51 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

I didn't see any (b)(5)

Can you provide me this info asap?

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



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Charlotte

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(b)(5)

Thx for your assistance. – m

(b)(5)

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Subject: 2019-nCoV regulatory science gaps

Takeaways from Monday's meeting on regulatory science gaps:

(b)(5)

Please let me know if I've omitted anything....

Best,
Robert

Robert W. Fisher, Ph.D.

Senior Advisor for CBRN and Pandemic Influenza

Office of Counterterrorism and Emerging Threats (OCET)

Office of the Chief Scientist, Office of the Commissioner

U.S. Food and Drug Administration

(w)301-796-8518

(m) (b)(6)

robert.fisher@fda.hhs.gov



From: Ashcraft, Charlotte [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3DEFAED236074242ACED487D77B09B47-CMASHCRAFT]
Sent: 2/20/2020 11:20:00 AM
To: Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Cason, Winona [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3434073fc4cc4b578c59ca60a5da91f8-Winona.Caso]
Subject: RE: 2019-nCoV regulatory science gaps NCTR Proposal

Thanks Tucker. That is correct.

(b)(5)

(b)(5)

Thanks,
Charlotte

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Sent: Thursday, February 20, 2020 10:18 AM
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Subject: RE: 2019-nCoV regulatory science gaps NCTR Proposal

Denise,

(b)(5)

(b)(5)

Thanks.

Tucker

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research



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Subject: RE: 2019-nCoV regulatory science gaps NCTR Proposal

(b)(5)

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Denise

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Sent: Thursday, February 20, 2020 9:12 AM

To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Here you are.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Craft, William
Sent: Wednesday, February 19, 2020 8:20 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:10 AM
To: Craft, William <William.Craft@fda.hhs.gov>

Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

Hi Doug,

Please do (b)(5)

Thank you!

From: Craft, William <William.Craft@fda.hhs.gov>

Sent: Wednesday, February 19, 2020 8:06 AM

To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>

Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

Marli,

Take a look at these and make sure I have captured everything. The data call is asking for (b)(5)

(b)(5)

(b)(5)

Keep in mind that this (b)(5)

Thanks for getting these estimates to me.

Feel free to call if you have any questions.

William Douglas Craft

Management Analyst

Office of Management

National Center for Toxicological Research,

U.S. Food and Drug Administration,

Phone: 870-543-7250

william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>

Sent: Wednesday, February 19, 2020 7:54 AM

To: Craft, William <William.Craft@fda.hhs.gov>

Subject: RE: 2019-nCoV regulatory science gaps

Sorry,

(b)(5)

(b)(5)

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:51 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

I didn't see any (b)(5)

Can you provide me this info asap?

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov



The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 2:59 PM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>; Foley, Steven <Steven.Foley@fda.hhs.gov>; Cerniglia, Carl <Carl.Cerniglia@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Thank you

From: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 8:32 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli, yes, go ahead and move forward.

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research



*"The contents of this message are mine
and do not reflect any position of the
U.S. Food & Drug Administration."*

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 8:31 AM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

I'd like to try, if Tucker agrees.

Marli

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 8:26 AM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

GM All:

The data call is due today. If you want to work with Doug Craft to put together an estimate for a project, I'm happy to submit. | (b)(5) |

(b)(5)

Thanks
Charlotte

From: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 8:01 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli, I am running this by Charlotte to get her opinion. Thanks.

Tucker

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research



"The contents of this message are mine

and do not reflect any position of the U.S. Food & Drug Administration.”

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:58 AM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Should we work to put one together for NCTR?

Marli

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:36 AM
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemarv.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi – just to close the loop on this – no need to this info to me as I understand each Center/office will be capturing its reg sci needs in its own budget line as opposed to submitting a consolidated reg sci request.

That said – OB would like to see a compiled list for reg sci – happy to help compile if folks want to send along info on our request. Thx

From: Mair, Michael
Sent: Monday, February 17, 2020 10:20 AM
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

(b)(5)

Thx for your assistance. – m

(b)(5)

From: Fisher, Robert <Robert.Fisher@fda.hhs.gov>

Sent: Wednesday, February 5, 2020 12:14 PM

To: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emilv.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemarv.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>

Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>

Subject: 2019-nCoV regulatory science gaps

Takeaways from Monday's meeting on regulatory science gaps:

(b)(5)

Please let me know if I've omitted anything....

Best,
Robert

Robert W. Fisher, Ph.D.

Senior Advisor for CBRN and Pandemic Influenza

Office of Counterterrorism and Emerging Threats (OCET)

Office of the Chief Scientist, Office of the Commissioner

U.S. Food and Drug Administration

(w) 301-796-8518

(m) (b)(6)

robert.fisher@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 2:17:23 PM
To: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
Subject: Re: Upcoming COVID Congressional Engagement

Thank you!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Date: February 20, 2020 at 1:52:50 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: Upcoming COVID Congressional Engagement

Hi Denise, I think this what you were referring to.

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Date: February 20, 2020 at 12:10:09 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, Berkowitz, Lauren <Lauren.Berkowitz@fda.hhs.gov>, Mettler, Erik <Erik.Mettler@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Upcoming COVID Congressional Engagement

A JIC colleague asked for a list of the hearings we discussed today. The list with some additions is below:

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Likley: Biweekly (trying to make this weekly) briefings for all Congressional staff – RADM Hinton would be the likely briefer

Likley/Possible: Weekly in-person briefings for Members of the Senate and House – Dr. Hahn would be the likely briefer

Possible: Hearing of the Senate Homeland Security and Government Affairs Committee - Dr. Hahn would be the likely witness

Andrew Tantillo

Deputy Director

Office of Legislation
U.S. Food and Drug Administration
O 301-796-8919 M (b)(6)
andrew.tantillo@fda.hhs.gov



From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/20/2020 4:30:39 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: SITREP for review
Attachments: 20_2019-nCoV Outbreak_FDA SITREP_20 February 2020.docx

thx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 6:08:29 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Coronavirus TPs/OMB
Attachments: FY 20 to FY 24 Coronavirus Outbreak Spending Estimates.xlsx

From: Tootle, William <William.Tootle@fda.hhs.gov>
Date: February 20, 2020 at 5:19:06 PM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Tyler, James <James.Tyler@fda.hhs.gov>
Subject: FW: Coronavirus TPs

Hi

Here are some talking points.

FDA Coronavirus Request

(b)(5)

(b)(5)

Bill Tootle

*Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705*

Phone: 301-796-4710/4579

From: Tootle, William

Sent: Thursday, February 20, 2020 4:57 PM

To: James Tyler <James.Tyler@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>

Subject: Coronavirus TPs

Here are some draft talking points for Keagan and Denise.

Bill Tootle

*Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705*

Phone: 301-796-4710/4579

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 6:22:40 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Coronavirus TPs
Attachments: FY 20 to FY 24 Coronavirus Outbreak Spending Estimates.xlsx

From: Tootle, William <William.Tootle@fda.hhs.gov>
Date: February 20, 2020 at 5:19:06 PM EST
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Tyler, James <James.Tyler@fda.hhs.gov>
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FDA Coronavirus Request

(b)(5)

(b)(5)

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Phone: 301-796-4710/4579

From: Tootle, William

Sent: Thursday, February 20, 2020 4:57 PM

To: James Tyler <James.Tyler@fda.hhs.gov>; Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>

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4041 Powder Mill Road,
Beltsville, MD 20705*

Phone: 301-796-4710/4579

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 7:18:15 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: READ: FOR CLEARANCE: Tweets for tomorrow- general and PHS All Hands promotion

From: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Sent: Thursday, February 20, 2020 4:01 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Ruberry, Erin <Erin.Ruberry@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: FOR CLEARANCE: Tweets for tomorrow- general and PHS All Hands promotion

Hi All,

Here are the suggested tweets for tomorrow's social media. Please review for your clearance and let me know if I should send on to Brad. I will be away from my computer after 7 p.m. tonight for a work function, but Brooke (copied here) can send anything forward in my absence.

Thanks very much,
Abby

(b)(5)

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Issues Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

Center for Tobacco Products

Office of Health Communication and Education

U.S. Food and Drug Administration

Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 7:23:44 PM
To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: FW: Upcoming COVID Congressional Engagement

I'll be attending the Hill briefings with Dr. Hahn on the highlighted days below – don't have times yet so sending for your awareness and our planning.

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Date: February 20, 2020 at 12:10:09 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, Berkowitz, Lauren <Lauren.Berkowitz@fda.hhs.gov>, Mettler, Erik <Erik.Mettler@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>
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Possible: Hearing of the Senate Homeland Security and Government Affairs Committee - Dr. Hahn would be the likely witness

Andrew Tantillo

Deputy Director

Office of Legislation
U.S. Food and Drug Administration

O 301-796-8919 M (b)(6)

andrew.tantillo@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 8:13:40 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: HHS International SPOTREP & SLB: COVID-19 (Update #100)
Attachments: COVID-19 SLB 20Feb20 Final.pdf

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Thursday, February 20, 2020 8:07 PM
To: Goldman, David <David.Goldman@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Thompson, Lori <Lori.Thompson@fda.hhs.gov>
Cc: FDA Commissioned Corps Affairs <FCCA@fda.hhs.gov>
Subject: FW: HHS International SPOTREP & SLB: COVID-19 (Update #100)

Today's ASPR Senior Leader Brief on COVID-19 (2019-nCoV) attached, and HHS international SPOTREP below.

UNCLASSIFIED // FOR OFFICIAL USE ONLY

HHS International SPOTREP: COVID-19 (Update #100)

Source: Interagency

What:

- **US confirmed cases: 15; Presumptive positive COVID-19 cases repatriated among Diamond Princess passengers pending U.S. confirmation testing**
- **4 asymptomatic COVID-19 positive cases : 2 were transported and 2 awaiting transport from Sacramento via air ambulance to a hospital in Spokane, Washington.**
- **The CDC issued a Level 1 travel advisory for people traveling to Japan, which advises travelers to avoid contact with sick people and wash hands with soap and water often.**
- **Please see the attached Senior Leader Brief (SLB)**

When: 20Feb20 1830ET

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Respectfully,

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Moran, Thomas (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9e89e2e38806436f95b8d8e3cea034e4-HHS-Thomas.]; Votava, Kathleen

(ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3026c1bb3ed447cc820d3ab43815a9f9-HHS-Kathlee]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Nicholls, Richard (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baae1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Durham, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae837bec7af74649ba95ae7f0b16c150-HHS-David.D]; Palosky, Stacey (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9be5b9b0f4ce483085a4fb39e02e5550-HHS-Stacey.]; Hooban, Christopher (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6c3a53c85874f8b868f3286b59f096f-HHS-Christo]; Delew, Nancy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6b9150131daa49fbbf486e3c4affcfc9-HHS-Nancy.D]; Mieryteran, Luis (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9fc5c6996a04850a3a9ebabb29631b7-HHS-Luis.Mi]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Trent-Adams, Sylvia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6d51a90464d433aa867020584eb2b61-HHS-Sylvia.]; Santiago, Yvonne (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=363fdbc8cc45dc9949ded0202a4cb4-HHS-Yvonne.]; Owens, Arne W (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=29dcc5bdf3ff4670b2076ff9995b70cd-HHS-Arne.Ow]; Kaul, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=84e3c1c04b5947108d277c0d50cfc257-HHS-Rachel.]; jeffrey.goodie@usuhs.edu; Bush, Laina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7596731c21444c8b89b13d454b403efd-HHS-Laina.B]; Kiley, Matthew (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5c6a9d23dfd740b6a92c7d48c1ba1379-HHS-Matthew]; Wainwright, Jacob (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=376e23c8d2ba4b8b8c0b53cc8158e206-HHS-Jacob.W]; Dulaigh, Joel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01f4f5f895214d4f8112c62d40ac50ce-HHS-Joel.Du]

Subject: Canceled: COVID-19 PMO Call

Attachments: COVID-19 PMO Call; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; COVID-19 PMO Call; Untitled Attachment; HHS COVID-19 PMO Description_FINAL.pdf; COVID-19 HHS PMO Daily Sync Call Agenda.docx; Untitled Attachment

Location: 610F/Dial In Below

Start: 2/24/2020 11:00:00 AM

End: 2/24/2020 12:00:00 PM

Show Time As: Free

Importance: High

Recurrence: Weekly

every Monday, Tuesday, Wednesday, Thursday, and Friday from 11:00 AM to 12:00 PM

Required Attendees: Pollard, Ashton (OS/IOS); Kadlec, Robert (OS/ASPR/IO); Shuy, Bryan (OS/ASPR/IO); McGowan, Robert (Kyle) (CDC/OD/OCS); Imbriale, Samuel (OS/ASPR/SIIM); McCreary, Kenneth (OS/ASPR/SPPR); Perdue, Christopher (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Phillips, Sally (OS/ASPR/SPPR); Pratt, Michael (OS/ASPA); Lenihan, Keagan (FDA/OC); Mair, Michael (FDA/OC); Hinton, Denise (FDA/OC); Johnston, Darcie (HHS/IEA); Zebley, Kyle (HHS/OS/OGA); Chang, William (HHS/OGC); Trueman, Laura (HHS/IEA); Marston, Hilary (NIH/NIAID) [E]; Kerr, Lawrence (HHS/OS/OGA); Fernandez, Jose (OS/OGA); Elvander, Erika (OS/OGA); Steven Valentine (HHS/OASH) (Steven.Valentine@hhs.gov); Schwartz, Erica (HHS/OASH); Grigsby, Garrett (HHS/OS/OGA); Moudy, Robin (OS/ASPR/SPPR); Gregg, William (Joe) (CDC/DDID/NCIRD/OD); Patel, Anita (CDC/DDID/NCIRD/OD); Dreyzehner, John (CDC/DDPHSIS/CPR/OD); McNellis, Robert (AHRQ/CEPI); Levine, Cheryl (OS/ASPR/EMMO); Kouzoukas, Demetrios

(CMS/OA); Kibunja, Julia (OS/OGA); Cochran, Norris (HHS/ASFR); Dasher, David (HHS/ASFR); Bettencourt, Alice (HHS/ASFR); Moughalian, Jen (HHS/ASFR) (Jen.Moughalian@hhs.gov); Hittle, Taylor (HHS/ASFR); Brookes, Brady (CMS/OA); Mignone, Alfred (FDA/OC); Jim Parker (HHS/IOS) (Jim.Parker@hhs.gov); Ann Agnew (HHS/IOS) (Ann.Agnew@hhs.gov); Steele, Danielle (HHS/IOS); Brooks, John (CMS/OA); Stannard, Paula (HHS/IOS); Brady, Will (HHS/IOS) (William.Brady@hhs.gov); Nick Uehlecke (HHS/IOS) (Nicholas.Uehlecke@hhs.gov); Keckler, Charles (HHS/IOS); Smith, Brad (CMS/OA); Giroir, Brett (HHS/OASH); Horska, Katerina (HHS/IOS); Arbes, Sarah (HHS/ASL) (Sarah.Arbes@hhs.gov); Baker, Michael (OS/IEA); Lincoln, Carol (OS/ASPR/EMMO); Newland, Matthew (OS/ASPR/BARDA); Oshansky, Christine (OS/ASPR/BARDA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Twomey, John K. (OS/IOS) (John.Twomey@HHS.GOV); Bradway, Courtney (HHS/ASL); Weahkee, Michael (IHS/HQ); Paden, Maris (HHS/ASL); Caitrin Shuy (HHS/ASFR) (Caitrin.Shuy@hhs.gov); Aasen, Adam (HHS/OS/OGA); Robertson, Lance (ACL); McGuffee, Tyler Ann (HHS/IOS); Monroe, Steve (CDC/DDPHSS/OLSS/OD); Donis, Ruben (OS/ASPR/BARDA); Engels, Thomas (HRSA); Cheever, Laura (HRSA); Macrae, Jim (HRSA); Morris, Tom (HRSA); Severino, Roger (HHS/OCR)

(b)(6)



HHS COVID-19
PMO Description...



COVID-19 HHS
PMO Daily Sync ...

From: Anderson, Erika [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=98606928B9A64EDFB25ABA1E3573FDFF-ERANDERS]
Sent: 2/21/2020 2:07:29 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 21, 2020 at 11:22:37 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Would chang

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 11:04 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed

(b)(5)

Otherwise, reads well to me!

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

From: Caliguiri, Laura
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika

<Erika.Anderson@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika

Tweets for today's clearance and flagging: (b)(5) TY.

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Issues Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

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Office of Health Communication and Education

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Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/21/2020 2:16:13 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me too – (b)(5)

Thank you!

Denise

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:07 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 21, 2020 at 11:22:37 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Would change (b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 11:04 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed (b)(5) Otherwise, reads well to me!

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Sent: Friday, February 21, 2020 10:57 AM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

From: Caliguiri, Laura

Sent: Friday, February 21, 2020 10:57 AM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika

Tweets for today's clearance and flagging

(b)(5)

TY.

(b)(5)

Abigail Capobianco, MA

Writer/Editor

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2019 Novel Coronavirus (COVID-19) IMG

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<http://www.fda.gov/>



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/21/2020 2:39:25 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: For urgent review: coronavirus, statement on inspections
Attachments: Statement draft 2.21.20_230pm.docx

Importance: High

Making sure you already weighed in along with ORA for alignment? Thanks

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: For urgent review: coronavirus, statement on inspections

Keagan, Denise, Erika-

For your urgent review, the draft statement on inspections. This has been JIC and OCC cleared. I am waiting to clear one point from ORA, which is noted in the statement. Following your review, we can get to Dr. Hahn.

I'll concurrently flag for ASPA.

Let me know if you have any questions, thanks!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.344.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/21/2020 2:45:00 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Just added (b)(5) this works – thanks!

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:30 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

For clearance, new in red, official specific acknowledgement.

(b)(5)

From: Caliguiri, Laura
Sent: Friday, February 21, 2020 2:16 PM
To: Heidi Rebello (Heidi.Rebello@fda.hhs.gov) <Heidi.Rebello@fda.hhs.gov>
Subject: QQ RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Erika and Denise have cleared including your note – are we good or should we wait for KL?

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:07 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 21, 2020 at 11:22:37 AM EST

To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Would change (b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 11:04 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed (b)(5) Otherwise, reads well to me!

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

From: Caliguiri, Laura
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika
Tweets for today's clearance and flagging (b)(5) TY.

(b)(5)

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Issues Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

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Office of Health Communication and Education

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Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/21/2020 3:03:55 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thumbs up.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:58 PM
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL or HR? Any objections?

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:45 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Re: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good by me.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 21, 2020 at 2:30:24 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

For clearance, new in red, official specific acknowledgement.

(b)(5)

From: Caliguiri, Laura
Sent: Friday, February 21, 2020 2:16 PM
To: Heidi Rebello (Heidi.Rebello@fda.hhs.gov) <Heidi.Rebello@fda.hhs.gov>
Subject: QQ RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Erika and Denise have cleared including your note – are we good or should we wait for KL?

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:07 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 21, 2020 at 11:22:37 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Would change (b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 11:04 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed (b)(5) Otherwise, reads well to me!

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

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Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika

Tweets for today's clearance and flagging: (b)(5) TY.

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Issues Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

Center for Tobacco Products

Office of Health Communication and Education

U.S. Food and Drug Administration

Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/21/2020 3:04:15 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

nope

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Would change

(b)(5)

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Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed

(b)(5)

Otherwise, reads well to me!

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+Heidi

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Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika

Tweets for today's clearance and flagging

(b)(5)

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Issues Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

Center for Tobacco Products

Office of Health Communication and Education

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Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Anderson, Erika [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=98606928B9A64EDFB25ABA1E3573FDFF-ERANDERS]
Sent: 2/21/2020 3:20:41 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebeee5ffeeb7f3d-Heather.Jan]
Subject: RE: For urgent review: coronavirus, statement on inspections
Attachments: Statement draft 2.21.20_230pm OPLIA edits.docx

A few edits and comments from me.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: For urgent review: coronavirus, statement on inspections

Keagan, Denise, Erika-

For your urgent review, the draft statement on inspections. This has been JIC and OCC cleared. I am waiting to clear one point from ORA, which is noted in the statement. Following your review, we can get to Dr. Hahn.

I'll concurrently flag for ASPA.

Let me know if you have any questions, thanks!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov



From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/21/2020 4:18:55 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: JIC Accomplishments and Goals Today_2020.02.21
Importance: High

Today's Accomplishments

- COS note to JIC members clarifying expectations and commitment (going later this PM)
- Dr. Hahn all-hands email to FDA employees (going later this PM)
- FDA Statement on Inspections – going through final clearance (going later this PM)
- Op-Ed on fraud through clearance
- Tweets:
 - NIAID news on remdesivir trial/cross-posting
 - FDA Statement on inspections
 - Dr. Hahn at PHS All-Hands w/photos
- Cleared 1st set of comprehensive FDA talkers on COVID-19
- Commissioner Chat filmed today

Future Items

(b)(5)

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 2/21/2020 4:35:51 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
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Subject: RE: For urgent review: coronavirus, statement on inspections
Attachments: Statement draft 2.21.20_430pm.docx

Thanks! I've incorporated all your feedback into this version. I'll clean up and move along. Thank you!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 21, 2020 4:13 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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Subject: RE: For urgent review: coronavirus, statement on inspections

Edits

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 21, 2020 3:56 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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Subject: RE: For urgent review: coronavirus, statement on inspections

Thank you both! Keagan, ok with you? I am happy to clean up and get into Dr. Hahn's HW over the weekend.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 3:49 PM
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: For urgent review: coronavirus, statement on inspections

Me too – thank you!

Denise

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>

Sent: Friday, February 21, 2020 3:21 PM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

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Let me know if you have any questions, thanks!

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Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.343.1956
Cell: (b)(6)
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Sent: 2/22/2020 1:30:20 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: CDC Key Points COVID-19 for February 21, 2020
Attachments: CDC Key Points (COVID-19) for February 21, 2020.pdf

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Date: February 21, 2020 at 10:05:20 PM EST
To: Goldman, David <David.Goldman@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>, Keller, Melanie <Melanie.Keller@fda.hhs.gov>, Thompson, Lori <Lori.Thompson@fda.hhs.gov>
Subject: FW: CDC Key Points COVID-19 for February 21, 2020

FYI- CDC Key Points on COVID-19 for today are attached. A good overall brief, succinctly presented.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



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To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbebee5ffe7f3d-Heather.Jan]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]
Subject: RE: flag—Request for comment on drugs at risk for shortage.

Thanks. Story posted: <https://www.axios.com/coronavirus-threatens-drug-shortage-318c9e7b-5d92-4a5e-b992-2478023c6d01.html>

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: February 23, 2020 at 8:55:51 AM EST
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: flag—Request for comment on drugs at risk for shortage.

Thanks Laura and Stephanie. It's well after 8am but I'm comfortable with the response you provided below, as they are from cleared talking points.

Best,

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Date: February 22, 2020 at 8:11:04 PM EST

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>

Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>

Subject: RE: flag—Request for comment on drugs at risk for shortage.

FYSA SC has run this by ASPA and working through CDER/JIC. She will respond closer to the 8am deadline.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Saturday, February 22, 2020 7:55 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>

Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>

Subject: RE: flag—Request for comment on drugs at risk for shortage.

(b)(5)

From: Caccomo, Stephanie

Sent: Saturday, February 22, 2020 7:15 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>

Subject: flag—Request for comment on drugs at risk for shortage.

Hi all—

Early flag on an axios story on an apparent list we compiled on 150 drugs at risk for shortage if outbreak continues. It's on hold for right now. I'm tracking down info and will keep you posted. Thx!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Date: February 22, 2020 at 7:01:15 PM EST

To: Finnen, April <April.Finnen@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>

Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: URGENT: Request for comment — urgent

Hey folks—

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Finnen, April <April.Finnen@fda.hhs.gov>

Date: February 22, 2020 at 6:52:43 PM EST

To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie

E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: RE: Request for comment — urgent

Here's what we have on this from the master talking points (I am not sure if these are OCC-cleared yet, but they went to OCC on Friday, and were pulled from cleared TPs and other cleared docs we have been using). Brooke – OK w/you?
Michael/Stephanie – defer to you on how much of this to send to reporter.

(b)(5)

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Sent: Saturday, February 22, 2020 6:12 PM

To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: Re: Request for comment — urgent

Hi all (b)(4) (b)(5)

Lorrie

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Date: February 22, 2020 at 5:49:40 PM EST

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: Re: Request for comment — urgent

Thanks—apologies for any redundancies, but adding CDER shortage sme’s just in case not on the jic list given the time urgency.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Date: February 22, 2020 at 5:46:54 PM EST

To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

Subject: Fwd: Request for comment — urgent

Hi JIC team,

Please see the inquiry below.

Thanks,

Michael

Michael Felberbaum

Senior Advisor

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell: (b)(6)

michael.felberbaum@fda.hhs.gov

From: Caitlin Owens (b)(6)

Date: February 22, 2020 at 5:44:50 PM EST

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Subject: Request for comment — urgent

Hi Michael, I've heard the FDA has a list of about 150 drugs that are at risk of shortage if the coronavirus situation gets worse in China. It includes antibiotics, generics and some single source branded drugs. I plan to write tonight, so if you could respond with input/comment ASAP, that'd be very helpful.

I'm aiming to publish by 6:45 or so, but I know that's not much time so can be flexible. Thanks!

--

Caitlin Owens

Axios

Reporter

c. [redacted] (b)(6)

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 2/23/2020 10:37:21 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbееее5ffееb7f3d-Heather.Jan]
CC: Stark, Angela [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d04b10a5e0ec40ffa2ebfedd711e83af-Angela.Star]
Subject: RE: flag—Request for comment on drugs at risk for shortage.

Thanks Denise! SC sent the link around.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, February 23, 2020 8:56 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: flag—Request for comment on drugs at risk for shortage.

Thanks Laura and Stephanie. It's well after 8am but I'm comfortable with the response you provided below, as they are from cleared talking points.

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From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 22, 2020 at 8:11:04 PM EST
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: flag—Request for comment on drugs at risk for shortage.

FYSA SC has run this by ASPA and working through CDER/JIC. She will respond closer to the 8am deadline.

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Saturday, February 22, 2020 7:55 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise

<Denise.Hinton@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>

Cc: Stark, Angela <Angela.Stark@fda.hhs.gov>

Subject: RE: flag—Request for comment on drugs at risk for shortage.

(b)(5)

From: Cacco, Stephanie

Sent: Saturday, February 22, 2020 7:15 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>

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Hi all—

Early flag on an axios story on an apparent list we compiled on 150 drugs at risk for shortage if outbreak continues. It's on hold for right now. I'm tracking down info and will keep you posted. Thx!

Stephanie Cacco

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Desk: 301.348.1956

Cell: (b)(6)

stephanie.cacco@fda.hhs.gov

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Date: February 22, 2020 at 7:01:15 PM EST

To: Finnen, April <April.Finnen@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>

Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS

<CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: URGENT: Request for comment — urgent

Hey folks—

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Desk: 301.348.1956

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stephanie.caccomo@fda.hhs.gov

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Date: February 22, 2020 at 6:52:43 PM EST

To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

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(b)(5)

(b)(5)

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To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

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Subject: Re: Request for comment — urgent

Hi all

(b)(4) (b)(5)

Lorrie

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Date: February 22, 2020 at 5:49:40 PM EST

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: Re: Request for comment — urgent

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From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: February 22, 2020 at 5:46:54 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: Fwd: Request for comment — urgent

Hi JIC team,

Please see the inquiry below.

Thanks,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov

From: Caitlin Owens (b)(6)
Date: February 22, 2020 at 5:44:50 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Request for comment — urgent

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--

Caitlin Owens
Axios
Reporter

c (b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/24/2020 6:53:00 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: WHO COVID-19 Situation Report #34 - 2/23/2020
Attachments: WHO Situation Report #34 COVID-19.pdf

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Date: February 23, 2020 at 11:50:28 PM EST
To: Goldman, David <David.Goldman@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Cc: FDA Commissioned Corps Affairs <FCCA@fda.hhs.gov>, Mahmud, Nasser <Nasser.Mahmud@fda.hhs.gov>
Subject: FW: WHO COVID-19 Situation Report #34 - 2/23/2020

WHO Situation Report attached.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/24/2020 11:41:29 AM
To: Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]
Subject: : For IMG Review - Needles and Face Masks
Attachments: remdensivir.docx; NEEDLES.docx; FACE MASKS.docx

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 24, 2020 11:38 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: For IMG Review

PRE-DECISIONAL, CONFIDENTIAL

Hi Michael and Tom –

Attached are close hold memos coming to us from HHS / WH.

By 12pm tomorrow, can IMG provide initial thoughts on these 3 sets of recommendations related to remdesivir, needles, and face masks? It would be most helpful to know where FDA has equities and if there are any key considerations we can communicate to HHS.

Please let me know if you have questions. Thanks in advance for your time in between everything else on your schedules.

Anand

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/24/2020 12:00:03 PM
To: Rawlings, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ae46d13993dc46e190ae70b61e1d4871-KRawling]
Subject: RE: Hoping for the best!

Thanks to the Lord!

From: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Sent: Monday, February 24, 2020 11:58 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Hoping for the best!

Thanks Denise.

(b)(6)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, February 24, 2020 11:54 AM
To: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Subject: Hoping for the best!

Oh my goodness –

(b)(6)

From: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Sent: Monday, February 24, 2020 7:15 AM
To: Choe, Lena <Lena.Choe@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: URGENT: Request for comment — urgent

Thanks for being in the loop yesterday evening.

(b)(6)

(b)(6)

(b)(5)

I'm trying to determine what's been shared for my awareness.

Kim

From: Choe, Lena <Lena.Choe@fda.hhs.gov>
Date: February 22, 2020 at 8:13:57 PM EST
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS

<CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: RE: URGENT: Request for comment — urgent

We are not aware of an FDA list of drugs at risk of shortage. I would like to share that there is a list of essential meds from a non-FDA source that has been circulating.

Vizient Identifies Essential Medications in Hospitals and Highlights Fragility of the Supply Chain

Vizient's List of Essential medications

CDER Comms is fine with this response (from our most recent statement) unless there are any other concerns.

Thanks,
Lena

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Saturday, February 22, 2020 7:54 PM

To: Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: RE: URGENT: Request for comment — urgent

(b)(5)

From: Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>

Sent: Saturday, February 22, 2020 7:25 PM

To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: Re: URGENT: Request for comment — urgent

I will let our comms folks check in, but from my conversations on Thursday and Friday in the Center this doesn't sound right. This may be a reference to checking in on the facilities in China or looking at essential medicines, but I don't believe this is accurate the way it is stated here.

From: "Courtney, Brooke" <Brooke.Courtney@fda.hhs.gov>

Sent: Saturday, February 22, 2020 7:10 PM

To: "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>,"Finnen, April" <April.Finnen@fda.hhs.gov>,"McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>,"Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>,"2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>,"Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>

CC: "Patel, Paras M" <Paras.Patel@fda.hhs.gov>,"Jensen, Valerie E" <Valerie.Jensen@fda.hhs.gov>,"CDER-ER-OPS <CDEREROPS@fda.hhs.gov>,"Hinton, Denise" <Denise.Hinton@fda.hhs.gov>,"Mair, Michael" <Michael.Mair@fda.hhs.gov>

Subject: Re: URGENT: Request for comment — urgent

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Date: February 22, 2020 at 7:01:15 PM EST

To: Finnen, April <April.Finnen@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: URGENT: Request for comment — urgent

Hey folks—

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Desk: 301.348.1956

Cell: (b)(6)

stephanie.caccomo@fda.hhs.gov

From: Finnen, April <April.Finnen@fda.hhs.gov>

Date: February 22, 2020 at 6:52:43 PM EST

To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: RE: Request for comment — urgent

Here's what we have on this from the master talking points (I am not sure if these are OCC-cleared yet, but they went to OCC on Friday, and were pulled from cleared TPs and other cleared docs we have been using). Brooke – OK w/you? Michael/Stephanie – defer to you on how much of this to send to reporter.

(b)(5)

(b)(5)

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>

Sent: Saturday, February 22, 2020 6:12 PM

To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;
2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie
E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: Re: Request for comment — urgent

Hi all - (b)(4) (b)(5)

Lorrie

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Date: February 22, 2020 at 5:49:40 PM EST

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-
nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie
E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>

Subject: Re: Request for comment — urgent

Thanks—apologies for any redundancies, but adding CDER shortage sme's just in case not on the jic list given the time
urgency.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Date: February 22, 2020 at 5:46:54 PM EST

To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Subject: Fwd: Request for comment — urgent

Hi JIC team,

Please see the inquiry below.

Thanks,

Michael

Michael Felberbaum

Senior Advisor

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell (b)(6)

michael.felberbaum@fda.hhs.gov

From: Caitlin Owens: (b)(6)
Date: February 22, 2020 at 5:44:50 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Request for comment — urgent

Hi Michael, I've heard the FDA has a list of about 150 drugs that are at risk of shortage if the coronavirus situation gets worse in China. It includes antibiotics, generics and some single source branded drugs. I plan to write tonight, so if you could respond with input/comment ASAP, that'd be very helpful.

I'm aiming to publish by 6:45 or so, but I know that's not much time so can be flexible. Thanks!

--

Caitlin Owens

Axios

Reporter

c (b)(6)

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/25/2020 10:46:38 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: RE: Action requested re: COVID-19 response
Attachments: SH Senate Update TPs 2.24.20.528.docx; Response By the Numbers 2.25.20.901am.docx

Hi - Can u provide more detail on what is wanted so we can provide more/better info?

(b)(5)

And, what can the JIC proactively communicate about – it can be updates or educate the public on FDA’s roles in each Center/ORA....

The JIC is working proactive comms every day – is something missing?

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 2/25/2020 3:35:39 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: Problem statement- RPDs
Attachments: N95-Challenges-022520-HHS-DRAFT.FDA.2.25.20.docx

From: Courtney, Brooke
Sent: Tuesday, February 25, 2020 3:30 PM
To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Subject: RE: Problem statement- RPDs

Hi Laura,

FDA (including CDRH) comments/edits are attached. We defer to CDC and ASPR on accuracy of the statistics. If you have any questions, just let us know.

Thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office); (b)(6) (cell)
brooke.courtney@fda.hhs.gov

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Tuesday, February 25, 2020 9:59 AM
To: Patel, Anita (CDC) <bop1@cdc.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Subject: RE: Problem statement- RPDs

All-

Please see attached the draft statement

(b)(5)

(b)(5)

(b)(5)

Please distribute within your agencies for comment/revisions and let me know if you think you can get feedback to my team by 3pm.

Thanks-

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov
Desk: 202-260-0666
Cell: (b)(6)

From: Wolf, Laura (OS/ASPR/SIIM)
Sent: Tuesday, February 25, 2020 7:19 AM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>
Subject: RE: Problem statement- RPDs

FYSA- had significant technology challenges overnight, so wrapping up the draft now. You'll have it shortly.

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
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From: Wolf, Laura (OS/ASPR/SIIM)
Sent: Monday, February 24, 2020 5:28 PM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>; Phillips, Sally (OS/ASPR/SPPR) <Sally.Phillips@hhs.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>
Subject: Problem statement- RPDs

Colleagues-

I will pull together tonight a (b)(5)

(b)(5)

(b)(5)

Laura

Laura Kwinn Wolf, Ph.D.

Director, Division of Critical Infrastructure Protection

HHS/ASPR

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From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/25/2020 5:13:25 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcded4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0ccb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P.
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Marc A. EOP/OMB (b)(6); Mroz, Sara K. EOP/NSC (b)(6); Troye, Olivia
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[/o=ExchangeLabs/ou=Exchange Administrative Group
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Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian
J. EOP/NSC (b)(6); Bakewell, Richard A (b)(6); Thomas, Gloria D (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS)
[/o=ExchangeLabs/ou=Exchange Administrative Group
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EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Sugarman,
AJ J. EOP/WHO (b)(6); Planning, David M. EOP/WHO (b)(6)
Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6); Greene Richard S.
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debbie.w.seguin (b)(6); william.ferrara (b)(6); Tobin, Elizabeth D. EOP/NSC
(b)(6); Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J
(b)(6); Music, Chris G. EOP/OMB (b)(6); Ali, Naushe (b)(6)
Burris, Meghan K. EOP/WHO (b)(6); Henning, Alexa A. EOP/WHO
(b)(6); Daravi, Roma S. EOP/WHO (b)(6); Horstman, John
H. EOP/WHO (b)(6); MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA)
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EOP/NSC (b)(6); Ulliyot, John L. EOP/NSC (b)(6); Stufft, Julie M.
EOP/NSC (b)(6); Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC
(b)(6); Davis, May M. EOP/WHO (b)(6); Lekan, Scott M (ACF)
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B.
EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6); Thallam, Satya
P. EOP/OMB (b)(6); Allen, Ronald G. EOP/NSC (b)(6); Schuchat,
Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB
(b)(6); Schroyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A
(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; Hinton, Denise
[/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D.
EOP/NSC (b)(6); Mesquita, Mario M (b)(6); Millard, Christopher
A (Chris) CTR OSD OUSD POLICY (USA) (b)(6); DL Chief of Staff Office
(b)(6); Ash, Deborah J. EOP/NSC
(b)(6); Reilly, Tom M. EOP/OMB (b)(6); Havranek, John

(b)(6) Dum, Christopher M (b)(6) FORET, VERNON T
(b)(6) Ellis, Michael J. EOP/WHO (b)(6) Blue, Matthew
(ODAG) Matthew.Blue@usdoj.gov; Decker, Matthew G. EOP/NSC (b)(6) JACKSTA,
LINDA L (b)(6) Parra, Yolanda A (b)(6) Carter, Hillary H. EOP/NSC
(b)(6) Galkowski, James J. EOP/WHO (b)(6) Tokumasu de
Silva, Miriam E (b)(6) Doyle, Emma K. EOP/WHO (b)(6) Lason, Adam
J. EOP/NSC (b)(6) McPheeME (b)(6) Carson, Tracy L (Geneva) (b)(6)
Bibo, David (b)(6) Dorko, Jeffrey (b)(6) Hughes, William C. (ODAG)
[William.C.Hughes@usdoj.gov]; Hamel, Michael A (Mike) CTR OSD OUSD POLICY (USA)
(b)(6) Syptak-Ramnath, Stephanie F (b)(6); david.short@dot.gov;
Isenberg, Daniel T CTR OSD OUSD POLICY (USA) (b)(6) Okediji, Adedeji E (Beijing)
(b)(6) De La Riva, Etienne EOP/NSC (b)(6) Morgan, Jameson A.
EOP/NSC (b)(6) Smith, Jason S. EOP/NSC (b)(6) Durie, Troy M.
EOP/CEA (b)(6) Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Sappenfield, Christine A
(b)(6); Eisenberg, John A. EOP/WHO (b)(6) Bai, Sue J. EOP/WHO
(b)(6) Hennessey, Millicent S. EOP/NSC (b)(6) Fritz, Jonathan D
(b)(6) Maycock, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M]; Knapper, Marc E
(b)(6) Nesheiwat, Julia EOP/NSC (b)(6) Nevins, Kristan K. EOP/WHO
(b)(6) Paz, Brooke L. EOP/WHO (b)(6) Thomi, Markus A.
EOP/NSC (b)(6) Coronavirus Global Response Coordination Unit
(b)(6) Goyer, Jim L. IV EOP/WHO
(b)(6)

Subject: SARS-CoV-2 (b)(5)
Location: EEOB SMS Large- IN PERSON

Start: 2/26/2020 11:00:00 AM
End: 2/26/2020 12:30:00 PM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

As discussed today, SAP Ruggiero will convene an in person (b)(5) on **February 26, 2020, from 11:00 A.M.-12:30 PM**

(b) (5)

Participants are expected to attend in person. With exception of CDC Atlanta, NIAD and FDA there will be no additional SVTC connections .

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

Please use the WAVES link to register for attendance. (b)(6)

Best Regards,

Phil

From: Ferro, Phil J. EOP/NSC (b)(6)
Sent: 2/25/2020 5:13:25 PM
To: Ferro, Phil J. EOP/NSC (b)(6); DL NSC Defense (b)(6); DL NSC Legal (b)(6); DL NSC NSA FO Staff (b)(6); DL NSC STRATCOM (b)(6); Droegemeier, Kelvin K. EOP/OSTP (b)(6); Daravi, Kamran S. EOP/WHO (b)(6); Grewe, Brenda L. EOP/NSC (b)(6); Deere, Judd P. EOP/WHO (b)(6); Ditto, Jessica E. EOP/WHO (b)(6); Yanick, Brittany M. EOP/WHO (b)(6); Hayes, Bradley F. EOP/OMB (b)(6); Smith, Gregory L. EOP/WHO (b)(6); Doster, Kim M. EOP/OSTP (b)(6); Gastfriend, Daniel Z. EOP/OMB (b)(6); Baum, Kristina R. EOP/OSTP (b)(6); Bicket, Mark C. EOP/OSTP (b)(6); Blair, Robert B. EOP/WHO (b)(6); Bonyun, Sean C. EOP/OSTP (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Campana, Alexandra D. EOP/WHO (b)(6); Grogan, Joseph J. EOP/WHO (b)(6); Hudson, Renee R. EOP/WHO (b)(6); Jack, Brian T. EOP/WHO (b)(6); Kan, Derek T. EOP/OMB (b)(6); Kratsios, Michael J. EOP/OSTP (b)(6); Lattimore, Tracie B. EOP/OSTP (b)(6); Lin, Merry S. EOP/WHO (b)(6); McKenna, Michael A. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Miles, Aaron R. EOP/OSTP (b)(6); Olmem, Andrew J. EOP/WHO (b)(6); Pataki, Tim A. EOP/WHO (b)(6); Ray, Paul J. EOP/OMB (b)(6); Wong, Anna W. EOP/CEA (b)(6); Walters, William (b)(6); Bonner, Maria K. EOP/WHO (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); DL NSC WMD (b)(6); Cetron, Martin (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0df896abcdd4e5d91d79a34c4b49ce9-HHS-mzc4-cd]; gary.c.rasicot (b)(6); amie.kalsbeek@dot.gov; Naar, Alex (FAA) [Alex.Naar@faa.gov]; Firoved, Aaron (b)(6); Limage, Julia (b)(6); Seffel, Gary A. EOP/NSC (b)(6); Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffb9dd983419fcd-HHS-olx1-cd]; Waterman, Paige E. EOP/OSTP (b)(6); Waterman, Elijah J. EOP/NSC (b)(6); Watson, Ian D. EOP/OSTP (b)(6); Biles, Amber D CDR USN OSD OUSD POLICY (USA) (b)(6); Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Tobert, Gwen M (b)(6); Scovitch, Joseph R (b)(6); Costello, Kelly E (b)(6); DL NSC IO (b)(6); DL NSC Asia (b)(6); DL NSC Press (b)(6); DL NSC Resilience (b)(6); DL NSC HSA FO Staff (b)(6); DL NSC Legislative (b)(6); DL NSC BATS (b)(6); Redd, John T (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d7be3c75e1c4375b5d6d2a315c581c5-HHS-John.Re]; Cornett, Elizabeth A CIV (USA) (b)(6); Thornton, Cody R CDR USPHS OSD OUSD POLICY (USA) (b)(6); Gulati, Neetu (b)(6); Liebschutz, Jennifer E. EOP/OMB (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Imize@usaid.gov; jslotnick@usaid.gov; Kendra Chittenden

[kchittenden@usaid.gov]; Boney, Virginia M. EOP/WHO (b)(6); Tully, Ryan M. EOP/NSC (b)(6); Frater, Eric M (b)(6); Christ, Katelyn E. EOP/NSC (b)(6); Weinberger, Collin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd4fd713e0de4d899676030918973af8-HHS-Collin.]; Landrum, Ryan P. EOP/NSC (b)(6); Rault, Nick M. EOP/NSC (b)(6); Hanna, Cory M. EOP/NSC (b)(6); Burton, Nicholas S. EOP/OMB (b)(6); Garufi, Marc A. EOP/OMB (b)(6); Mroz, Sara K. EOP/NSC (b)(6); Troye, Olivia EOP/NSC (b)(6); Carlson, Eric J (b)(6); McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Lowry, Patrick J. EOP/NSC (b)(6); Cartin, Josh M. EOP/NSC (b)(6); Kanapathy, Ivan J. EOP/NSC (b)(6); Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Cavanaugh, Brian J. EOP/NSC (b)(6); Bakewell, Richard A (b)(6); Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Butler, Jay C (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5889356ccdc748039523698679f9d269-HHS-jcb3-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Ruggiero, Anthony J. EOP/NSC (b)(6); Brett Armstrong - D1R [brett.armstrong@gsa.gov]; paul.detitta@gsa.gov; Marwaha, Brianna C (b)(6); Carstens, Virgil W (b)(6); Hassell, David (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=31a03c44931f42afbbdffac04264888a-HHS-David.H]; McMillin, Virginia D. EOP/WHO (b)(6); Telle, Adam R. EOP/WHO (b)(6); Sugarman, AJ J. EOP/WHO (b)(6); Planning, David M. EOP/WHO (b)(6); Feddersen, Brett (FAA) [Brett.Feddersen@faa.gov]; Padget, Larry G (b)(6); Greene Richard S. (GH/HIDN) [USAID] [rgreene@usaid.gov] [rgreene@usaid.gov]; Baehr, James S. EOP/WHO (b)(6); Magrino, Christopher (b)(6); debbie.w.seguin (b)(6); william.ferrara (b)(6); Tobin, Elizabeth D. EOP/NSC (b)(6); Jonas, Seth H. EOP/NSC (b)(6); Martin, Gregory J (b)(6); Music, Chris G. EOP/OMB (b)(6); Ali, Nausher (b)(6); Burris, Meghan K. EOP/WHO (b)(6); Henning, Alexa A. EOP/WHO (b)(6); Daravi, Roma S. EOP/WHO (b)(6); Horstman, John H. EOP/WHO (b)(6); MUSIC, FRANCESCA Christy CIV OSD OUSD POLICY (USA) (b)(6); Wilson, John Mark M. EOP/NSC (b)(6); Martin, Michael E. EOP/NSC (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Sadat, Mir H. EOP/NSC (b)(6); Gray, Alexander B. EOP/NSC (b)(6); Rubini, Jeffrey H. EOP/NSC (b)(6); Jlyot, John L. EOP/NSC (b)(6); Stufft, Julie M. EOP/NSC (b)(6); Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Browne, Lisa Y. EOP/NSC (b)(6); Davis, May M. EOP/WHO (b)(6); Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Chafin, Kelly B. EOP/NSC (b)(6); Bailey, Drew M. EOP/OMB (b)(6); Thallam, Satya P. EOP/OMB (b)(6); Allen, Ronald G. EOP/NSC (b)(6); Schuchat, Anne (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=848b7544f27d4a2a9554a80e78d002fc-HHS-ac1-cd]; Bain, Ally P. EOP/OMB (b)(6); Schmoyer, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc457b777d57409d961efa1d49e1b4ba-HHS-Michael]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Champagne, Joshua D. EOP/NSC (b)(6); Mesquita, Mario M (b)(6); Millard, Christopher A (Chris) CTR OSD OUSD POLICY (USA) (b)(6); DL Chief of Staff Office (b)(6); Ash, Deborah J. EOP/NSC (b)(6); Reilly, Tom M. EOP/OMB (b)(6); Havranek, John (b)(6)

(b)(6); Dumm, Christopher M (b)(6); FORET, VERNON T
(b)(6); Ellis, Michael J. EOP/WHO (b)(6); Blue, Matthew
(ODAG) [Matthew.Blue@usdoj.gov]; Decker, Matthew G. EOP/NSC (b)(6); JACKSTA,
LINDA L (b)(6); Parra, Yolanda A (b)(6); Carter, Hillary H. EOP/NSC
(b)(6); Galkowski, James J. EOP/WHO (b)(6); Tokumasu de
Silva, Miriam E (b)(6); Doyle, Emma K. EOP/WHO (b)(6); Lason, Adam
J. EOP/NSC (b)(6); McPheeME (b)(6); Carson, Tracy L (Geneva) (b)(6)
Bibo, David (b)(6); Dorko, Jeffrey (b)(6); Hughes, William C. (ODAG)
[William.C.Hughes@usdoj.gov]; Hamel, Michael A (Mike) CTR OSD OUSD POLICY (USA)
(b)(6); Syptak-Ramnath, Stephanie F (b)(6); david.short@dot.gov;
Isenberg, Daniel T CTR OSD OUSD POLICY (USA) (b)(6); Okediji, Adedeji E (Beijing)
(b)(6); De La Riva, Etienne EOP/NSC (b)(6); Morgan, Jameson A.
EOP/NSC (b)(6); Smith, Jason S. EOP/NSC (b)(6); Durie, Troy M.
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0dabd5952b2430eab81c4f6d3adee42-HHS-Brett.M]; Knapper, Marc E
(b)(6); Nesheiwat, Julia EOP/NSC (b)(6); Nevins, Kristan K. EOP/WHO
(b)(6); Paz, Brooke L. EOP/WHO (b)(6); Thomi, Markus A.
EOP/NSC (b)(6); Coronavirus Global Response Coordination Unit
(b)(6); Goyer, Jim L. IV EOP/WHO
(b)(6)

Subject: SARS-CoV-2 (b)(5)
Location: EEOB SMS Large- IN PERSON

Start: 2/26/2020 11:00:00 AM
End: 2/26/2020 12:30:00 PM
Show Time As: Tentative

Recurrence: (none)

Dear Colleagues,

As discussed today, SAP Ruggiero will convene an in person (b)(5) on **February 26, 2020, from 11:00 A.M.-12:30 PM**

(b)(5)

Participants are expected to attend in person. With exception of CDC Atlanta, NIAD and FDA there will be no additional SVTC connections .

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

Please use the WAVES link to register for attendance. (b)(6)

Best Regards,

Phil

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/25/2020 7:32:03 PM
To: Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]; Keller, Melanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3cb276c1cf8e4fdebedd2fd559d11be9-KELLERME]; Thompson, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45bad77196f04331af573e6be45be08b-Lori.Thomps]
Subject: FW: HHS International SPOTREP: COVID-19 (Update #111)
Attachments: COVID-19 SLB 25Feb20 FINAL.pdf

FYI- attached is today's ASPR Senior Leadership Brief for COVID-19 and below is an HHS SPOTREP.

UNCLASSIFIED // FOR OFFICIAL USE ONLY

HHS International SPOTREP: COVID-19 (Update #111)

Source: Interagency

What:

- Current global cases are 80,116 and 2,697 global deaths
- Miramar NAS will be closing down after today and being returned to DoD; One additional positive case was transferred from Lackland AFB to UNMC
- NIAID clinical trial began Feb 21 at UNMC to evaluate the safety and efficacy of Remdesivir as a therapeutic agent
- For further information, please see the attached Senior Leader Brief (SLB)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/25/2020 8:10:09 PM
To: Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Nabakowski, Andrei [Andrei.Nabakowski@fda.hhs.gov]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]
Subject: FYSA: FDA 2019-nCOV SITREP - 25 Feb 2020
Attachments: 23_2019-nCoV Outbreak_FDA SITREP_25 February 2020.docx

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 5:03 PM
Subject: FDA 2019-nCOV SITREP - 25 Feb 2020

Hi,

Attached for your situational awareness is the 25 February FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support. -Michael

From: Cason, Winona [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3434073FC4CC4B578C59CA60A5DA91F8-WINONA.CASO]
Sent: 2/26/2020 8:58:31 AM
To: Ashcraft, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3defaed236074242aced487d77b09b47-Cmashcraft]; Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Thanks for the quick response, Charlotte. Based on this morning's call, sounds like FDA (and other OPDIVs, I'm sure) are under the gun to turn this around rapidly and concisely.

Winona Cason

Associate Director for Management/Executive Officer

National Center for Toxicological Research, Jefferson, AR
Office of Management
U.S. Food and Drug Administration
Tel: 870-543-7351
winona.cason@fda.hhs.gov



From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 7:56 AM
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Cason, Winona <Winona.Cason@fda.hhs.gov>
Subject: FW: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

FYI....

From: Ashcraft, Charlotte
Sent: Wednesday, February 26, 2020 7:54 AM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>
Cc: FDA Budget Formulation - NCTR <FDABudgetFormulation-NCTR@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Good Morning Ken,
The spreadsheet is locked by another user, so I've attached our information here only.

(b)(5)

(b)(5)

If you have any questions, please let me know.

Thanks
Charlotte

From: Willis, Ken <Ken.Willis@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:39 PM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Cc: FDA Budget Formulation - NCTR <FDABudgetFormulation-NCTR@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Thanks Charlotte. Can you please also let us know

(b)(5)

(b)(5)

Ken D. Willis, MBA
Lead Budget Analyst
U.S. Food and Drug Administration (FDA)
Office of Budget (OB)
Division of Budget Formulation
4041 Powder Mill Road
Office 72115A
Phone: 301-796-4372
Email: Ken.Willis@fda.hhs.gov



OFFICE OF FINANCE BUDGET
AND ACQUISITIONS
#OFBAWhereTheStewardshipHappens

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 5:28 PM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>
Cc: FDA Budget Formulation - NCTR <FDABudgetFormulation-NCTR@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

NCTR information is completed.

Thanks,
Charlotte

"A lie doesn't become truth, wrong doesn't become right and evil doesn't become good just because it's accepted by a majority." Booker T. Washington

From: Willis, Ken <Ken.Willis@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:20 PM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Thanks for letting me know. I am out of it now.

Ken D. Willis, MBA
Lead Budget Analyst
U.S. Food and Drug Administration (FDA)
Office of Budget (OB)
Division of Budget Formulation
4041 Powder Mill Road
Office 72115A
Phone: 301-796-4372
Email: Ken.Willis@fda.hhs.gov



OFFICE OF FINANCE BUDGET
AND ACQUISITIONS
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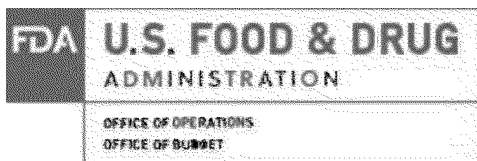
From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 5:20 PM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Hi Ken,
You have the file locked. 😊 Can you let me know when it is available?

Thanks,
Charlotte

"A lie doesn't become truth, wrong doesn't become right and evil doesn't become good just because it's accepted by a majority." Booker T. Washington

From: FDA Office of Budget <FDAOfficeofBudget@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 3:44 PM
To: FDA Budget Formulation Contacts <FDABudgetFormulationContacts@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Green, Jamie <Jamie.Green@fda.hhs.gov>; Enoch, Bobby <Bobby.Enoch@fda.hhs.gov>; Yates, Connie <Connie.Yates@fda.hhs.gov>; Buchanan, Noni <Noni.Buchanan@fda.hhs.gov>; Tan, William <William.Tan@fda.hhs.gov>; Akparewa, Amy <Amy.Akparewa@fda.hhs.gov>; Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Cc: FDA Budget Formulation-OB <FDABudgetFormulationOB@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Matthews-Ockiya, Swynice <Swynice.Matthews-Ockiya@fda.hhs.gov>; Grant, Leonard D <Leonard.Grant@fda.hhs.gov>; FDA Executive Officers <ExecOfficer@fda.hhs.gov>
Subject: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category



Division of Budget Formulation and Program Alignment (DBFPA) Data Call

DATE: February 25, 2020
DATA CALL #: 20-06-F
MEMO FOR: FDA Budget Formulation Community
FROM: Bill Tootle
Director, Office of Budget
SUBJECT: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category
Due Dates: 10:30 am Wednesday, February 26, 2020

Affected Organizations: All FDA Centers, ORA and HQ Offices

Purpose: To breakout the estimates of FDA's total anticipated costs related to the Coronavirus outbreak among four priorities categories identified by FDA leadership to ensure FDA can provide technical assistance to Congress on our anticipated needs, both in the short-term (FY 2020), and in the outyears (FY 2021 – FY 2024).

Center/Office Action Required: Update the table in SharePoint to identify the estimated costs and timing (for the appropriate fiscal year(s)) of the following:

(b)(5)

In the description section, please distinguish the activities that will be performed in FY 2020 from those anticipated to be performed in the outyears (FY 2021 – FY 2024).

OB has provided an updated spreadsheet and SharePoint location to collect this information. This data call is separate from the data call regarding the (b)(5) (b)(5). It is also different from the weekly data collection that is due each Wednesday. Please use the FY 2020 to FY 2024 Coronavirus Cost Estimates by Category spreadsheet via SharePoint to enter your center or office's information.

In the file, you will notice several rows under each center/office. This is for you to break out the funding among the high priority categories identified above. You will need to provide a short description of the activities you would carry out under each priority category. You will also notice a fifth row labeled "Other." Every effort should be made to capture your costs in one of the four categories of activities identified in the bullets above. The Other category is intended to give you a place to identify any major activities not captured in the four primary categories.

Insert your Center or Office's respective numbers, and save the FY 2020 to FY 2024 Coronavirus Cost Estimates by Category spreadsheet under the same file name. Please close out of the Excel file after saving your center or office's updates. **Do not upload a new version of the file** as that will overwrite any changes made by other centers and offices.

Fill out only columns and cells that are highlighted in yellow and only the rows that correspond to your Center or Office. Do **not** alter or delete data pertaining to another Center or add rows to the spreadsheet.

Background: The seriousness of the coronavirus outbreak makes this a high priority activity so we want to be able to provide Congress with our best estimates of our anticipated level of effort to address our responsibilities. Each center/office will need to provide their estimated costs to OB by **10:30 am Wednesday (2/26/2020)**.

DBFPA Contact: Please contact Bill Tootle, Eric Wong, Ken Willis, CT Tsai, or your DBF Analyst with any questions or concerns. Updated contact information can be found on the Office of Budget - Formulation SharePoint Home Page.

OB | Office of Budget

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/26/2020 10:35:08 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FYI: For review this morning: statement on supply chain
Attachments: Supply chain draft statement_2.26.20 occ cleared.docx

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 9:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: For review this morning: statement on supply chain

Keagan, Denise, Erika-

Attached is a draft statement, to issue from Dr. Hahn, on the status of the supply chain across FDA regulated products. (b)(5) we think it will be very helpful to reporters who have been individually pinging for this same information.

(b)(5)

This is JIC and OCC cleared. Once you clear, I will send to HHS for HHS/WH review and put in Dr. Hahn HW. Fingers crossed we could issue tomorrow!

Thanks!

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/26/2020 10:39:07 AM
To: Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]
Subject: FYSA: For review this morning: statement on supply chain
Attachments: Supply chain draft statement_2.26.20 occ cleared.docx

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 9:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: For review this morning: statement on supply chain

Keagan, Denise, Erika-

Attached is a draft statement to issue from Dr. Hahn on the status of the supply chain across FDA regulated products. (b)(5) we think it will be very helpful to reporters who have been individually pinged for this same information.

(b)(5)

This is JIC and OCC cleared. Once you clear, I will send to HHS for HHS/WH review and put in Dr. Hahn HW. Fingers crossed we could issue tomorrow!

Thanks!

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov



From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 2/26/2020 12:23:00 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"
Attachments: Supply Situation for Essential Medications for Severe CVD_to KL_02252020.docx; WH List of Essential Medications_FDA cover memo_to KL_02252020.docx

Get back for Navarro and something the HHS team might want to be inserted in PCC process.

From: Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:44 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Reply to Dr. Peter Navarro regarding Supply Situation for "List of Essential Medications for Severe CVD Infection"

Good Afternoon Keagan,

I am attaching the CDER-cleared response to Dr. Navarro's request for information on the supply of products on the "List of Essential Medications for Severe CVD Infection." I'm also attaching a suggested cover memo. Please let me know if you have any questions or need additional information.

Thank you,
Jessica

Jessica Bernstein, MPH
Office of Executive Programs, CDER
Office phone: 240-402-0524

From: DeBord, Kristin (OS/ASPR/SPPR) [Kristin.DeBord@hhs.gov]
Sent: 2/26/2020 1:54:38 PM
To: Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Pollard, Ashton (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0eba064633c94d69ac56385c0972e3da-HHS-Ashton.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffc7b280b7bc-HHS-Samuel.]; McCreary, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33bccf04199d4fd6948f0b933ce1623e-HHS-Kenneth]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddd-HHS-Kyle.Ze]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]
CC: Aviles, Natalie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=819bb9680d734e22944efc33d32f4f6f-HHS-Natalie]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; SOC Information Management Section Chief (OS/ASPR) [SOC.IM@hhs.gov]; Espinosa, Gregorio (OS) [/o=ExchangeLabs/ou=Exchange

Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e58a1f33cc27486a9b7b2c8a789ed328-HHS-Gregori]; Birmingham, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3f23d4114514e90908a9928c8ce526e-HHS-uvk7-cd]; Maples, David L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47e6281952984095b3359c680e0387b9-HHS-idr0-cd]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63ed25c8067c4b838dbb689460ce0486-HHS-Susan.O]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Asher, Jason (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f026ebf942de4865944a935e4b2106dd-HHS-Jason.A]; Clay, Matt A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd2be2512f44fae9f59ac4aa02820c9-HHS-Matt.Cl]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]

Subject: COVID-19 PMO - Supply Chain document

Attachments: N95-Challenges-HHS-FINAL-022620.docx

All,
For your awareness – Attached is the draft issues paper on N95 respirators I provided an overview of during this morning’s meeting. It has gone to the WH for coordination in the COVID-19 Supply Chain Coordination Working Group for their input on potential courses of action. This is a draft document that was coordinated through ASPR, CDC, and FDA.
Best,
Kristin



N95-Challenges-...

Kristin L DeBord, PhD
Acting Deputy Assistant Secretary
Office of Strategy, Policy, Planning, and Requirements (SPPR)
Office of the Assistant Secretary for Preparedness and Response (ASPR)

HEALTH AND HUMAN SERVICES (HHS) | O’Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) 401-5250 | m. (b)(6)
kristin.debord@hhs.gov | www.phe.gov

-----Original Appointment-----

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>

Sent: Friday, February 21, 2020 11:15 AM

To: Mango, Paul (HHS/IOS); Pollard, Ashton (OS/IOS); Kadlec, Robert (OS/ASPR/IO); Shuy, Bryan (OS/ASPR/IO); McGowan, Robert (Kyle) (CDC/OD/OCS); Imbriale, Samuel (OS/ASPR/SIIM); Mccreary, Kenneth (OS/ASPR/SPPR); Perdue, Christopher (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Phillips, Sally (OS/ASPR/SPPR); Pratt, Michael (OS/ASPA);

Lenihan, Keagan (FDA/OC); Mair, Michael (FDA/OC); Hinton, Denise (FDA/OC); Johnston, Darcie (HHS/IEA); Zebley, Kyle (HHS/OS/OGA); Chang, William (HHS/OGC); Trueman, Laura (HHS/IEA); Marston, Hilary (NIH/NIAID) [E]; Kerr, Lawrence (HHS/OS/OGA); Fernandez, Jose (OS/OGA); Elvander, Erika (OS/OGA); Valentine, Steven (HHS/OASH); Schwartz, Erica (HHS/OASH); Grigsby, Garrett (HHS/OS/OGA); Moudy, Robin (OS/ASPR/SPPR)

Cc: Aviles, Natalie (OS/ASPR/SIIM); Knutson, Donna (CDC/DDNID/NCEH/OD); Austin, Meredith (uscg.mil); OS Secretarys Operations Center; SOC Information Management Section Chief (OS/ASPR); Espinosa, Gregorio (OS/ASPR/SIIM); Bermingham, John (CDC/DDPHSIS/CPR/DEO); Maples, David L. (CDC/DDPHSIS/CPR/DEO); Harrison, Brian (HHS/IOS); Berger, Sherri (CDC/OCOO/OD); Hall, Bill (HHS/ASPA); Orsega, Susan (OS/OASH); Wong, Diana (OS/ASPR/SIIM); Asher, Jason (OS/ASPR/SIIM) (CTR); Clay, Matt (OS/ASPR/SIIM) (CTR)

Subject: COVID-19 PMO Call

When: Wednesday, February 26, 2020 10:00 AM-10:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: 610F/Dial In Below

(b)(6)

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/26/2020 6:03:19 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]
Subject: FW: FDA 2019-nCOV SITREP - 26 Feb 2020
Attachments: 24_2019-nCoV Outbreak_FDA SITREP_26 February 2020.docx

FYI- attached is today's COVID-19 SITREP, already sent to the AEG (so RADM Hinton has it, but cc'ing her again here for awareness).

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



FDA U.S. FOOD & DRUG
ADMINISTRATION

From: Measer, Gregory <Gregory.Measer@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 5:09 PM
To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: FW: FDA 2019-nCOV SITREP - 26 Feb 2020

FYI -- the attached 26 Feb SITREP has been posted to SharePoint. Thanks.

Best,
Greg

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 5:02 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey

<Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdo, Mark <Mark.Abdo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>

Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.O'Callaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Measer, Gregory <Gregory.Measer@fda.hhs.gov>

Subject: FDA 2019-nCoV SITREP - 26 Feb 2020

Hi,

Attached for your situational awareness is the 26 February FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support. -Michael

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/27/2020 11:10:54 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Internal, Confidential: Emulate | Organs-on-Chips | and COVID19

okay

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Thursday, February 27, 2020 11:01 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Internal, Confidential: Emulate | Organs-on-Chips | and COVID19

I will ask around:

(b)(5)

From: Mair, Michael
Sent: Thursday, February 27, 2020 11:00 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Internal, Confidential: Emulate | Organs-on-Chips | and COVID19

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, February 27, 2020 10:46 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Internal, Confidential: Emulate | Organs-on-Chips | and COVID19
Importance: High

Interest – reg sci?

From: Geraldine Hamilton <geraldine.hamilton@emulatebio.com>
Sent: Wednesday, February 26, 2020 5:01 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Fitzpatrick, Suzanne <Suzanne.Fitzpatrick@fda.hhs.gov>; Sebastian Hernandez <sebastian.hernandez@emulatebio.com>
Subject: Emulate | Organs-on-Chips | and COVID19
Importance: High

Hello Denise,

Hope all is well with you. I wanted to reach out to you regarding the COVID-19 virus and the potential for the Emulate Organs-on-Chip technology to be applied to answer key questions related to the emerging novel coronavirus outbreak.

We have been communicating with our key contacts at (b)(4) based on their feedback and the questions being raised about the virus. We came up with 3 main ideas on how the Emulate platform could potentially be useful for the ongoing outbreak in two main ways:

(b)(4)

(b)(4)

3. Efficacy and safety testing of potential antiviral therapeutic candidates

Here are links to some of our publications demonstrating the potential to use Organs-on-Chips for infectious disease:

<https://www.biorxiv.org/search/lung%2Bchip>

<https://www.biorxiv.org/content/10.1101/2020.02.03.931170v1>

<https://www.sciencedirect.com/science/article/abs/pii/S1931312819304160>

We are currently putting together a one-page document to capture this

(b)(4)

(b)(4)

Do you think the FDA would like to be involved in this effort in some way? Would be great to discuss further and get your insights.

This may be very short notice but I plan to be in DC on Thursday - we could explore meeting in person if schedule aligns but totally understand that you must be super busy right now.

Look forward to hearing from you.

Best wishes,
Geraldine.

emulate

Geraldine A. Hamilton, PhD
President and Chief Scientific Officer

(b)(6)

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emulate

Geraldine A. Hamilton, PhD
President and Chief Scientific Officer

(b)(6)

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transmitting software viruses, but we advise you to carry out your own virus checks on any attachment to this message. We cannot accept liability for any loss or damage caused by software viruses. The information contained in this communication may be confidential and may be subject to the attorney-client privilege. If you are the intended recipient and you do not wish to receive similar electronic messages from us in the future then please respond to the sender to this effect.

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/27/2020 3:09:54 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: TPs
Attachments: TPs_27 FEB 2020.docx

Hows this

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 2/27/2020 4:55:19 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: Fit-testing checklist development
Attachments: Respirator Enforcement Policy for COVID-19 to RAs (12pm_2-26-20).docx

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 27, 2020 at 4:43:02 PM EST
To: Patel, Anita (CDC) <bop1@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
Cc: Sweatt.Loren.E@dol.gov <Sweatt.Loren.E@dol.gov>, Brown, Christopher (DOL.GOV) <brown.christopher.k@dol.gov>
Subject: FW: Fit-testing checklist development

CDC and FDA colleagues-

Our colleagues at OSHA have asked for review of a draft document that enables enforcement discretion for their staff in the field regarding annual fit-testing requirements so long as certain criteria are met. Also see questions below, if there is any feedback on triggers. Please send comments back to PDAS Sweatt and Mr. Brown from OSHA.

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.sgov.gov
Desk: 202-260-0666
Cell: (b)(6)

From: Sweatt, Loren E. - OSHA <Sweatt.Loren.E@dol.gov>
Sent: Wednesday, February 26, 2020 1:27 PM
To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Cc: Mandy, Edens (DOL) <edens.mandy@dol.gov>; Brown, Christopher (DOL.GOV) <brown.christopher.k@dol.gov>
Subject: RE: Fit-testing checklist development

Dr. Wolf,

Attached please find a draft, deliberative document relating to the issue of annual fit testing. OSHA looks forward to comment from HHS/ASPR. The question of timing the release of the document remains open. Is HHS going to make a declaration of a shortage, or state concern regarding the current supply or supply chain issues? Looking forward to further discussion on this. And, apologies for the delay on our end. I am always overly optimistic about the clearance process. Thanks.

Loren

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/27/2020 7:02:31 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: supply chain statement
Attachments: Supply chain draft statement_2.27.20_final to issue_545pm.docx

Thanks – no further comments from me.

Denise

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Thursday, February 27, 2020 5:50 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: supply chain statement

OCC reviewing now.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/27/2020 7:29:53 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Today's COVID-19 HHS International SPOTREP, SLB, and CDC Situation Report
Attachments: COVID-19 SLB 27Feb20 Final.pdf

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Thursday, February 27, 2020 7:06 PM
To: Goldman, David <David.Goldman@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Cc: FDA Commissioned Corps Affairs <FCCA@fda.hhs.gov>
Subject: Today's COVID-19 HHS International SPOTREP, SLB, and CDC Situation Report

FDA PHS leadership,

Today's ASPR SLB attached and HHS SPOTREP info below.

Senior Leadership Brief pages 1-7
CDC Situation Report pages 8-13

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HHS International SPOTREP: COVID-19 (Update #117)

Source: Interagency

What:

- Current global cases are 82,066 and 2,800 global deaths.
- CDC submitted updated guidance on optimizing the use of N95 respirators in healthcare settings to include use of stockpiled N95 respirators beyond the manufacturer-intended shelf life and a check sheet to help healthcare facilities prioritize the order of implementation.
- On February 26, CDC confirmed an infection with the virus that causes COVID-19 in a person, within the U.S., who reportedly did not have relevant travel history or exposure to another COVID-19 patient.
- President Trump announced Vice President Mike Pence will oversee National Level COVID-19 Task Force.

For further information, please see the attached Senior Leader Brief (SLB), which includes the 27Feb20 CDC SITREP for Novel Coronavirus.

When: 27Feb20 1858ET

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From: Diana Brainard [Diana.Brainard@gilead.com]
Sent: 2/27/2020 10:00:56 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: connection with Gilead re COVID-19

Dear Denise,

That sounds perfect. Thank you for your prompt response.

Kind regards,
Diana

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, February 27, 2020 6:50 PM
To: Diana Brainard <Diana.Brainard@gilead.com>
Subject: [EXTERNAL] RE: connection with Gilead re COVID-19

Dear Diana,

Thank you for your email and offer to be of further assistance.

I appreciate Gilead's work with the Office of Infectious Disease and am hopeful remdesivir will prove to be an effective treatment for COVID-19.

I will contact you with questions as needed.

Very respectfully,

Denise

RADM Denise M. Hinton
Chief Scientist
Office of the Chief Scientist
Office of the Commissioner
U.S. Food and Drug Administration
U.S. Public Health Service
(301) 796-1090 (o)

From: Diana Brainard <Diana.Brainard@gilead.com>
Sent: Thursday, February 27, 2020 9:12 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: connection with Gilead re COVID-19

Dear Denise,

I'm reaching out to you at the suggestion of Rachel Sherman. I lead the virology group at Gilead and, as such, have been running our remdesivir program and response to the COVID-19 outbreak within Gilead.

Rachel shared that the Emerging Threats group reports to you, and I didn't know if we could be of assistance in any way. We are working very effectively with the Antiviral Division in terms of our clinical development plans.

I'd be happy to jump on the phone for an introductory call, or feel free to reach out should any questions on your part arise.

Kind regards,
Diana

Diana M Brainard, MD
Senior Vice President
Virology Therapeutic Area
Gilead Sciences, Inc
Tel: 650-522-4761

From: Rath, Prakash (FDA) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673DB6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/28/2020 8:01:18 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: Request for most current remarks/TPs
Attachments: FDA DLG Update 2.28.20 .docx; Master TPs_Week of 2.24.20.docx

Good morning Denise,

Attached are the TP's for the DLG that have been modified from a briefing Dr. Hahn is giving this morning (b)(5).
(b)(5) I don't know the DLG audience, but of course, please feel free to adjust the TP's to best suite the time and audience (b)(5)
(b)(5)

Also attached are master TP's for you to review in case ransom questions come up (not curated, just pulled from SP site). Please let me know if you have any questions ahead of time, and I'll see you this afternoon.

Thanks,
Prakash

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, February 27, 2020 10:05 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Subject: RE: Request for most current remarks/TPs

No problem – I see all over the news about reported drug shortages.

Thank you!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Thursday, February 27, 2020 10:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Request for most current remarks/TPs

Hi Denise,

We'll pulling together the TP's and I'll send something tonight, or early tomorrow. There's a lot of last minute edits due to all the activity tonight! For the afternoon briefing, you don't need to give comments, and I may need to bring the QA at the last minute.

Thanks,
Prakash

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, February 27, 2020 8:57 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Subject: Request for most current remarks/TPs

Hi Prakash,

May I have a copy of the most current remarks/talking points when you have an opportunity? I will be participating in the Disaster Leadership Group (DLG) meeting tomorrow morning at 1045 for Dr. Hahn. The purpose of this DLG is to gather HHS and interagency senior leaders to provide Departmental updates on COVID-19 activities. (b)(5) Then I have the Bicameral Staff Briefing in the afternoon with you.

Thanks,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/28/2020 9:18:51 AM
To: Nayak, Rajesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8a765c4c21b441a936fa746058a83e4-Rnayak]
Subject: RE: Research Outlines How Drug in Clinical Trial for Coronavirus Works

24/7 and is it ever evolving!

From: Nayak, Rajesh <Rajesh.Nayak@fda.hhs.gov>
Date: February 28, 2020 at 9:17:32 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Nayak, Rajesh <Rajesh.Nayak@fda.hhs.gov>
Subject: RE: Research Outlines How Drug in Clinical Trial for Coronavirus Works

You're welcome. I figured you'd be involved with COVID. Have a great weekend!


From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 28, 2020 8:16 AM
To: Nayak, Rajesh <Rajesh.Nayak@fda.hhs.gov>
Subject: Re: Research Outlines How Drug in Clinical Trial for Coronavirus Works

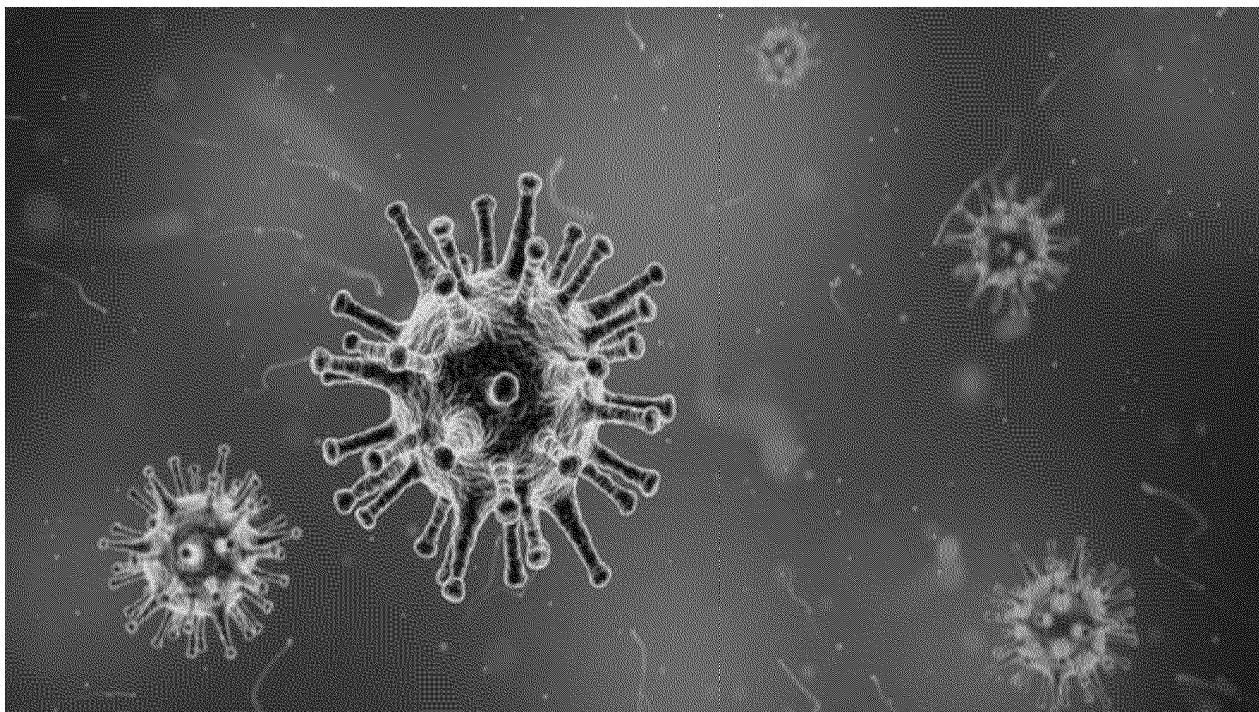
Thank you for sending this!

From: Nayak, Rajesh <Rajesh.Nayak@fda.hhs.gov>
Date: February 28, 2020 at 8:58:05 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Nayak, Rajesh <Rajesh.Nayak@fda.hhs.gov>
Subject: FW: Research Outlines How Drug in Clinical Trial for Coronavirus Works

FYI

Research Outlines How Drug in Clinical Trial for Coronavirus Works

 Feb 28, 2020 | By Molly Campbell, Science Writer, Technology Networks



Credit: Pixabay



Molly Campbell

Science Writer

@mollyrcampbell

Read Time: 1 min

A new study published in the *Journal of Biological Chemistry* outlines how an antiviral drug that is currently being tested in patients with the novel coronavirus (COVID-19), remdesivir, works.

Antiviral drugs are not yet approved for managing human coronaviruses, which is creating a wealth of challenges in the current efforts to contain the outbreak of COVID-19 which is caused by the SARS-CoV-2 virus. In order to survive and replicate, viruses must possess molecular machinery that can generate copies of their genetic material.



ARTICLE

Are We Heading for a Coronavirus Pandemic?

READ MORE

Coronaviruses are known to replicate their genetic material via an enzyme called RNA-dependent RNA polymerase. Remdesivir, developed by [Gilead Sciences](#), is a nucleotide analogue that was originally created for the treatment of the Ebola virus.

Studies in cell culture and animal models have demonstrated that the drug has a wide range of antiviral effects against a number of viruses, including coronaviruses. In this study, scientists used polymerase enzymes from the coronavirus that causes Middle East Respiratory Syndrome (MERS) to further explore remdesivir's mechanism of action.

The work was led by [Matthias Götte](#), a virologist and professor at the University of Alberta, Edmonton. He said: "It hasn't been easy to work with these viral polymerases". Due to this factor, previous work exploring the drug's function has been slow.

Götte and team discovered that the polymerase enzymes are able to incorporate remdesivir into their structure as it resembles an RNA building block, thereby "confusing" the enzyme. Upon this incorporation, the enzyme can no longer add more RNA subunits, halting the replication of the virus' genetic material.



VIDEO

What Actually Happens If You Get Coronavirus?

WATCH NOW

Why does this happen? The scientists suggest that the RNA containing remdesivir is a strange shape and therefore doesn't fit into the enzyme. To prove this hypothesis, they would need to obtain structural data on the enzyme and the synthesized RNA.

Remdesivir has not been approved as a drug anywhere in the world. According to Gilead, results from a clinical trial with COVID-19 patients in China are expected in April.

Reference: Gordon et al. (2020). The antiviral compound remdesivir potently inhibits RNA-dependent RNA polymerase from Middle East respiratory syndrome coronavirus. *Journal of Biological Chemistry*. DOI: 10.1074/jbc.AC120.013056.

From: Goldman, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A9C6C3E900B4771876C53FA24C1172B-DAVID.GOLDM]
Sent: 2/28/2020 3:25:55 PM
To: Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Nabakowski, Andrei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c8bcecc310c4e45a5012d47d40886e1-NABAKOWSKIA]
Subject: RE: 2-28-2020 Update: FDA Commissioned Corps Weekly Deployment Report

Randy, thanks for this suggestion. My only concern is in

(b)(5)

(b)(5)

From: Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Sent: Friday, February 28, 2020 2:56 PM
To: Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: RE: 2-28-2020 Update: FDA Commissioned Corps Weekly Deployment Report
Importance: High

SUGGESTION: If the decision is to

(b)(5)

(b)(5)

Best Regards,

*Randy L. Anderson, M.S., R.Ph, GWCPM
FDA Commissioned Corps Senior Advisor*

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FDA Applicant Help Desk: 888-478-4340 or e-mail: jobs@fda.hhs.gov

From: Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>
Sent: Friday, February 28, 2020 2:04 PM
To: Goldman, David <David.Goldman@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Subject: RE: 2-28-2020 Update: FDA Commissioned Corps Weekly Deployment Report

That makes sense to me. But let me defer to CAPT Nabakowski regarding the feasibility of implementing that suggestion.

From: Goldman, David <David.Goldman@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:15 PM
To: Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Subject: RE: 2-28-2020 Update: FDA Commissioned Corps Weekly Deployment Report

(b)(5)

From: Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>
Sent: Friday, February 28, 2020 12:47 PM
To: FDA Executive Officers <ExecOfficer@fda.hhs.gov>
Cc: FDA CC CCLRs <FDACCLiaisons@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Subject: 2-28-2020 Update: FDA Commissioned Corps Weekly Deployment Report

Good afternoon Executive Officers,

Below you will find information on FDA officers rostered/deployed/demobilized associated with the Coronavirus response, reflecting changes received to date. If you have questions regarding the numbers below, please do not hesitate to contact your Center/Office Commissioned Corps Liaison. Please know that we are available to work collaboratively with you and your Center/Office Commissioned Corps Liaison to address any questions you might have.

Thanks!
Darian

- **Total of 143 (+11) FDA officers have been involved in COVID-19 (2019-nCoV) response.**
 - **66 (-4) officers are deployed* (per scheduled departure date; departure not confirmed).**
 - **21 (+11) officers are rostered* to deploy.**
 - **56 (+4) officers confirmed demobilized.**
- ***Listed "STATUS" is generally determined by scheduled dates of deployment. "START_DATE" in past or present classifies "Deployed" status, and "START_DATE" in future classifies "Rostered" status. This means that some officers listed as "deployed" could potentially have had their travel delayed, and still pending. These dates and status can change swiftly depending on operational decisions, and we will seek to reconcile ahead. Please note that we continue to seek reconciled lists from RDB, but we do not receive updates beyond initial deployment notifications apart from some requests for extension (and we do not receive all of those). **This is an important point- some of the officers listed as "deployed" may not have received travel orders from ASPR or through RDB. For demobilized status, FCCA's approach is to seek confirmation that an officer has actually returned before any change in a listed "deployed" status to "demobilized".****

FDA COVID-19 Mission Status by Center			
ACF Repatriation Mission	Corona Virus Screening	Corona Virus Support	Total

	Deployed	Rostered	Demobilized	Deployed	Rostered	Demobilized	Deployed	Rostered	Demobilized	
CBER				1	1		2	1	2	7
CDER			2	20	7	10	17	3	11	70
CDRH			1	1			4			6
CFSAN						3	1			4
CTP							5	1	3	9
CVM				1					1	2
OC			1		1	1	1		1	5
ORA	1		2	9	7	4	3		14	40
Total	1	0	6	32	16	18	33	5	32	143*

*Current as of 2/28/2020

SERNO	LAST_NAME	FIRST_NAME	RANK	CATEGORY	BUREAU	SCHED_START_DATE	SCHED_END_DATE	MISSION	M
(b)(6)	ANSAH	KOFI	CAPT	PHARM	CDER	1/27/2020	2/12/2020	ACF Repatriation Mission	De
	TAWWAB	NURI	LCDR	PHARM	CDER	1/27/2020	2/11/2020	ACF Repatriation Mission	De
	SNYDER	LEON	LCDR	HSO	CDRH	1/28/2020	2/21/2020	ACF Repatriation Mission	De
	STEVENS	JAVONNA	LCDR	PHARM	OC	1/27/2020	2/11/2020	ACF Repatriation Mission	De
	DRASKI	LAURA	CAPT	SCI	ORA	1/28/2020	2/21/2020	ACF Repatriation Mission	De
	TRAN	QUYNH ANH	LCDR	PHARM	ORA	1/27/2020	2/14/2020	ACF Repatriation Mission	De
	VALLES	KARLA	LCDR	PHARM	ORA	2/12/2020	3/2/2020	ACF Repatriation Mission	De
(b)(6)	ELEKWACHI	OLUCHI	CDR	PHARM	CBER	TBD	TBD	Corona Virus Screening	Re
	XU	LEI	CDR	MED	CBER	2/19/2020	3/18/2020	Corona Virus Screening	De
	ADAMS	GRAFTON	CAPT	NURSE	CDER	2/14/2020	2/22/2020	Corona Virus Screening	De
	ADELEYE	CELESTINA	CDR	PHARM	CDER	TBD	TBD	Corona Virus Screening	Re

(b)(6)	BARLEY	STACY	CAPT	NURSE	CDER	2/26/2020	3/25/2020	Corona Virus Screening	De
	BUI	YEN ANH	LCDR	PHARM	CDER	2/15/2020	3/14/2020	Corona Virus Screening	De
	CARTER	LONICE	LT	NURSE	CDER	3/2/2020	3/15/2020	Corona Virus Screening	Re
	CHERRY-FRANCE	CHERONDA	CDR	NURSE	CDER	3/2/2020	3/15/2020	Corona Virus Screening	Re
	CHU	DAN-MY	CDR	SCI	CDER	2/26/2020	2/27/2020	Corona Virus Screening	De
	COHEN	REBECCA	CDR	NURSE	CDER	2/29/2020	3/13/2020	Corona Virus Screening	Re
	CROWLEY	ALISEA	CDR	PHARM	CDER	2/3/2020	2/16/2020	Corona Virus Screening	De
	DALESSANDRO	DOMENIC	LCDR	PHARM	CDER	2/15/2020	3/14/2020	Corona Virus Screening	De
	DIAK	PETER	CAPT	PHARM	CDER	2/14/2020	3/13/2020	Corona Virus Screening	De
	FERRETTI-ACETO	VICTORIA	CDR	PHARM	CDER	2/2/2020	3/1/2020	Corona Virus Screening	De
	FINN	JOSE	CDR	HSO	CDER	1/28/2020	2/28/2020	Corona Virus Screening	De
	FULLER	BARBARA	CAPT	NURSE	CDER	2/22/2020	3/6/2020	Corona Virus Screening	De
	HOWARD	CORWIN	LT	PHARM	CDER	2/14/2020	2/28/2020	Corona Virus Screening	De
	IMAM	MALIK	LCDR	PHARM	CDER	2/3/2020	2/16/2020	Corona Virus Screening	De
	JAYASEKARA	PUSHPA	LT	SCI	CDER	2/3/2020	2/16/2020	Corona Virus Screening	De
	JOHNSON	GLENDOLYNN	CDR	PHARM	CDER	2/15/2020	2/28/2020	Corona Virus Screening	De
	KIT	BRIAN	CAPT	MED	CDER	2/8/2020	2/23/2020	Corona Virus Screening	De
	KONG	YOON	CDR	PHARM	CDER	2/14/2020	3/2/2020	Corona Virus Screening	De

(b)(6)	KWENDE	ZERA	LCDR	PHARM	CDER	2/14/2020	3/13/2020	Corona Virus Screening	De
	LERNER	RUBY	CAPT	NURSE	CDER	2/15/2020	2/28/2020	Corona Virus Screening	De
	MANIWANG	JANICE	CAPT	PHARM	CDER	TBD	TBD	Corona Virus Screening	Re
	OGBONNA	CASMIR	LT	PHARM	CDER	2/14/2020	2/26/2020	Corona Virus Screening	De
	PARK	SYLVIA	LT	PHARM	CDER	2/2/2020	3/16/2020	Corona Virus Screening	De
	READY	TRAVIS	LCDR	PHARM	CDER	2/21/2020	3/5/2020	Corona Virus Screening	De
	SAMUELS	SHERBET	CAPT	NURSE	CDER	2/3/2020	2/23/2020	Corona Virus Screening	De
	SANSONE	VINCENT	CAPT	PHARM	CDER	2/15/2020	3/14/2020	Corona Virus Screening	De
	SCOTT	KIMBERLY	CDR	NURSE	CDER	3/1/2020	3/14/2020	Corona Virus Screening	Re
	TAYLOR	EDWARD	LT	PHARM	CDER	2/8/2020	2/21/2020	Corona Virus Screening	De
	TIWARI	RUBY	LCDR	PHARM	CDER	TBD	TBD	Corona Virus Screening	Re
	TRAN	TRANG	CDR	PHARM	CDER	2/3/2020	2/16/2020	Corona Virus Screening	De
	VU	HONG	LCDR	PHARM	CDER	1/27/2020	2/29/2020	Corona Virus Screening	De
	WEARNE	EVAN	LCDR	PHARM	CDER	2/14/2020	3/13/2020	Corona Virus Screening	De
	WONG	JENNIE	LCDR	PHARM	CDER	2/17/2020	3/16/2020	Corona Virus Screening	De
	WONG	REBECCA	LCDR	PHARM	CDER	2/24/2020	3/23/2020	Corona Virus Screening	De
	ZEBALLOS	MONICA	CAPT	PHARM	CDER	2/15/2020	3/14/2020	Corona Virus Screening	De
BELSITO	LJUCA	CAPT	NURSE	CDRH	2/14/2020	3/2/2020	Corona Virus Screening	De	

(b)(6)	CALCI	KEVIN	CAPT	EHO	CFSAN	1/27/2020	2/16/2020	Corona Virus Screening	De
	CHIEMENA	ANYANWU	LT	NURSE	CFSAN	2/2/2020	2/16/2020	Corona Virus Screening	De
	CHO	CHUNG	LCDR	HSO	CFSAN	2/3/2020	2/16/2020	Corona Virus Screening	De
	LINKENHOKER	JAN	CDR	VET	CVM	2/1/2020	2/29/2020	Corona Virus Screening	De
	BERTULFO	FRANCIS	CDR	HSO	OC	1/29/2020	2/22/2020	Corona Virus Screening	De
	LARSON	MARK	LT	NURSE	OC	3/2/2020	3/15/2020	Corona Virus Screening	Re
	BELL	NICOLE	LCDR	HSO	ORA	2/13/2020	3/12/2020	Corona Virus Screening	De
	CHANG	WILLIAM	LT	ENG	ORA	2/15/2020	2/28/2020	Corona Virus Screening	De
	CHOI	SUSANNA	CAPT	NURSE	ORA	2/29/2020	3/13/2020	Corona Virus Screening	Re
	DIDONNA	DANIELLE	CDR	HSO	ORA	2/19/2020	3/3/2020	Corona Virus Screening	De
	DUFF	MATTHEW	LCDR	PHARM	ORA	TBD	TBD	Corona Virus Screening	Re
	ENG	JENNIE	LT	HSO	ORA	2/25/2020	3/25/2020	Corona Virus Screening	De
	ESUZOR	GIDEON	LT	NURSE	ORA	2/8/2020	3/7/2020	Corona Virus Screening	De
	FISHER	CARMEN	CDR	NURSE	ORA	2/8/2020	2/21/2020	Corona Virus Screening	De
	GAZARIAN	DMITRY	LT	PHARM	ORA	3/3/2020	4/2/2020	Corona Virus Screening	Re
KELM	TRACI	LCDR	NURSE	ORA	2/8/2020	2/21/2020	Corona Virus Screening	De	
LE	CAROLINE	CDR	PHARM	ORA	2/2/2020	3/1/2020	Corona Virus Screening	De	

(b)(6)	LOWE	DAVID	LCDR	HSO	ORA	2/29/2020	3/13/2020	Corona Virus Screening	Re
	LYGHT	RICHARD	LCDR	PHARM	ORA	TBD	TBD	Corona Virus Screening	Re
	MANGIGIAN	STEPHANIE	CDR	NURSE	ORA	2/29/2020	3/13/2020	Corona Virus Screening	Re
	OGAN	ROBERT	CAPT	EHO	ORA	1/27/2020	2/29/2020	Corona Virus Screening	De
	ROBINSON	CAROL	LCDR	NURSE	ORA	2/29/2020	3/13/2020	Corona Virus Screening	Re
	RUSH	STEVEN	LT	PHARM	ORA	2/26/2020	3/25/2020	Corona Virus Screening	De
	SANDVIG	ERIK	LCDR	HSO	ORA	2/2/2020	2/16/2020	Corona Virus Screening	De
	SMITH	NICHOLAS	LCDR	NURSE	ORA	2/8/2020	3/7/2020	Corona Virus Screening	De
STRACENER	SHAUN	LT	ENG	ORA	2/3/2020	2/16/2020	Corona Virus Screening	De	

(b)(6)	DUNN	JESSICA	LT	SCI	CBER	2/20/2020	3/4/2020	Corona Virus Support	De
	ERTEL	DONALD	CDR	HSO	CBER	2/8/2020	2/16/2020	Corona Virus Support	De
	KELLY	JOSEPH	LCDR	HSO	CBER	3/7/2020	3/20/2020	Corona Virus Support	Re
	NASIRAH	MALCOLM	LCDR	PHARM	CBER	2/8/2020	2/22/2020	Corona Virus Support	De
	STEELE	MATTHEW	LCDR	SCI	CBER	2/18/2020	3/7/2020	Corona Virus Support	De
	BANDUKWALA	ABBAS	LCDR	ENG	CDER	2/24/2020	3/8/2020	Corona Virus Support	De
	BENNETT	MARCO	CAPT	SCI	CDER	TBD	TBD	Corona Virus Support	Re
	BIRCH-SMITH	POSTELLE	CAPT	PHARM	CDER	2/10/2020	2/23/2020	Corona Virus Support	De
BIZJAK	TARA	CDR	ENG	CDER	3/1/2020	3/17/2020	Corona Virus Support	Re	

(b)(6)	BROWN	RAICHELL	CDR	PHARM	CDER	2/25/2020	3/9/2020	Corona Virus Support	De
	BURNS	ASHLEY	LCDR	PHARM	CDER	2/8/2020	2/21/2020	Corona Virus Support	De
	CHANCEY	JASON	CDR	PHARM	CDER	2/3/2020	2/17/2020	Corona Virus Support	De
	COOGAN	ANDREW	LCDR	PHARM	CDER	2/8/2020	2/20/2020	Corona Virus Support	De
	CUI	MINGLEI	CDR	SCI	CDER	2/11/2020	2/24/2020	Corona Virus Support	De
	DAM	TRAMARA	LT	PHARM	CDER	2/11/2020	2/25/2020	Corona Virus Support	De
	DEXTER	PAUL	CAPT	HSO	CDER	2/8/2020	2/23/2020	Corona Virus Support	De
	ECHOLES	FRED	CDR	NURSE	CDER	2/6/2020	2/20/2020	Corona Virus Support	De
	FLOTILDES	CHARMAINE	CDR	NURSE	CDER	2/20/2020	3/4/2020	Corona Virus Support	De
	GONZALEZ- MERCADO	CARLOS	LCDR	PHARM	CDER	2/24/2020	3/8/2020	Corona Virus Support	De
	HALL	JAMES	LCDR	ENG	CDER	2/25/2020	3/9/2020	Corona Virus Support	De
	HALLMAN	TONI	LCDR	NURSE	CDER	2/20/2020	3/4/2020	Corona Virus Support	De
	HAMMOND	JILL	CAPT	ENG	CDER	1/29/2020	2/11/2020	Corona Virus Support	De
	HOARD	MARNA	CDR	HSO	CDER	2/22/2020	3/6/2020	Corona Virus Support	De
	HOLLINGER	KATHERINE	CAPT	VET	CDER	3/3/2020	3/16/2020	Corona Virus Support	Re
	HSU	WENCHI	LT	ENG	CDER	2/21/2020	3/4/2020	Corona Virus Support	De
	KIM	ANDREW	CDR	PHARM	CDER	2/20/2020	3/3/2020	Corona Virus Support	De

(b)(6)	LAROSE	JI HYUN	LCDR	PHARM	CDER	2/17/2020	3/1/2020	Corona Virus Support	De
	MATHEW	SHINY	LCDR	SCI	CDER	2/11/2020	2/24/2020	Corona Virus Support	De
	MCMILLAN	STEFEN	CDR	NURSE	CDER	2/6/2020	2/20/2020	Corona Virus Support	De
	PRICE	DUSTIN	CDR	NURSE	CDER	2/14/2020	3/2/2020	Corona Virus Support	De
	RHEE	SUSAN	LCDR	PHARM	CDER	2/22/2020	3/2/2020	Corona Virus Support	De
	RHIEU	STEVE	LT	ENG	CDER	2/24/2020	3/8/2020	Corona Virus Support	De
	THOMPSON	CHRISTINA	CDR	PHARM	CDER	2/28/2020	3/12/2020	Corona Virus Support	De
	TU	YAJUN	LT	PHARM	CDER	2/24/2020	3/8/2020	Corona Virus Support	De
	VOLPE	CAROLYN	CDR	PHARM	CDER	2/18/2020	3/2/2020	Corona Virus Support	De
	VOQUI	JESSICA	LCDR	PHARM	CDER	2/18/2020	3/2/2020	Corona Virus Support	De
	BROWNING	STEPHEN	LT	ENG	CDRH	2/18/2020	3/2/2020	Corona Virus Support	De
	KANG	ROBERT	CDR	PHARM	CDRH	2/24/2020	3/8/2020	Corona Virus Support	De
	PAPAZIAN	RAFFI	LCDR	ENG	CDRH	2/26/2020	3/10/2020	Corona Virus Support	De
	STEFFEN	SCOTT	LCDR	SCI	CDRH	2/24/2020	3/8/2020	Corona Virus Support	De
	GORDON	SUZAN	CAPT	DIET	CFSAN	2/19/2020	3/3/2020	Corona Virus Support	De
	BAIDEN	KENIA	LCDR	NURSE	CTP	2/11/2020	2/25/2020	Corona Virus Support	De
BASILIO	JEFFREY	LCDR	HSO	CTP	2/8/2020	2/20/2020	Corona Virus Support	De	

(b)(6)

EJIKE-KING	LACREISHA	LT	SCI	CTP	3/5/2020	3/18/2020	Corona Virus Support	Re
GAHL	ROBERT	LT	SCI	CTP	2/24/2020	3/8/2020	Corona Virus Support	De
GU	MICHAEL	LCDR	ENG	CTP	2/14/2020	2/27/2020	Corona Virus Support	De
KANAKRI	MUHAMMAD	LCDR	PHARM	CTP	1/29/2020	2/11/2020	Corona Virus Support	De
KATHERINE	DREW	LT	ENG	CTP	2/24/2020	3/8/2020	Corona Virus Support	De
PETERS	KRISTINA	CDR	PHARM	CTP	2/24/2020	3/8/2020	Corona Virus Support	De
VALVERDE	ROBERTO	LCDR	HSO	CTP	2/22/2020	3/4/2020	Corona Virus Support	De
CRAREY	EMILY	LCDR	HSO	CVM	2/15/2020	2/23/2020	Corona Virus Support	De
BROUNSTEIN	DANIEL	CDR	HSO	OC	2/19/2020	3/3/2020	Corona Virus Support	De
JIGGENS	TIMOTHY	CAPT	EHO	OC	2/8/2020	2/22/2020	Corona Virus Support	De
ALBRIGHT	HIEN	CDR	EHO	ORA	2/10/2020	2/22/2020	Corona Virus Support	De
BESSETTE	GREGORY	LCDR	ENG	ORA	2/15/2020	2/26/2020	Corona Virus Support	De
BOEHNEN	KENNETH	CDR	NURSE	ORA	2/8/2020	2/18/2020	Corona Virus Support	De
BRASWELL	DAWN	CDR	ENG	ORA	2/8/2020	2/21/2020	Corona Virus Support	De
BUTTKE	THIDA	LCDR	EHO	ORA	2/5/2020	2/18/2020	Corona Virus Support	De
HUFFMAN	CARL	CDR	HSO	ORA	2/5/2020	3/2/2020	Corona Virus Support	De
LENHART	AUDRA	LCDR	NURSE	ORA	2/7/2020	2/22/2020	Corona Virus Support	De

(b)(6)	MITCHELL-LEE	YOLANDA	CDR	HSO	ORA	2/6/2020	2/19/2020	Corona Virus Support	De
	MORRISON	MATTHEW	LCDR	HSO	ORA	2/15/2020	2/23/2020	Corona Virus Support	De
	MUELLER	ERIC	CAPT	PHARM	ORA	2/5/2020	2/20/2020	Corona Virus Support	De
	NGUYEN	BINH	CDR	PHARM	ORA	2/24/2020	3/8/2020	Corona Virus Support	De
	PAMBOUKIAN	RUIQING	CDR	SCI	ORA	2/15/2020	2/25/2020	Corona Virus Support	De
	SAVALIA	VARSHA	CAPT	ENG	ORA	2/20/2020	3/4/2020	Corona Virus Support	De
	SRAM	JACQUELINE	CDR	SCI	ORA	2/8/2020	2/18/2020	Corona Virus Support	De
	WIREMAN	JOSHUA	CDR	PHARM	ORA	2/3/2020	2/14/2020	Corona Virus Support	De
	WOOLRIDGE	CAPRI	LTJG	EHO	ORA	2/5/2020	2/18/2020	Corona Virus Support	De
	YAMBOT	MARCUS	LCDR	ENG	ORA	2/5/2020	2/16/2020	Corona Virus Support	De

Darian Tarver, CAPT, USPHS
Director

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(C) (b)(6)
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From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 2/28/2020 4:01:47 PM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

See edits in red and in yellow below.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 28, 2020 3:55 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

For your approval OCC has cleared the following tweets on the supply chain statement.

Supply Chain Tweets

@SteveFDA Account
Individual tweets--- To be spread out

(b)(5)

3/1/20

2. See my update on how @US_FDA is monitoring the supply chain of FDA-regulated products and working to mitigate shortages during the #coronavirus outbreak: [LINK TO SUPPLY CHAIN STATEMENT]

(b)(5)

2/29/20

Thread 1—Drug shortage:

(b)(5)

2. The shortage is due to an issue with manufacturing an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients.

3. We are working with the manufacturer of this drug as well as other manufacturers to mitigate this shortage and will do everything possible to mitigate it. #COVID19

4. We have contacted over 180 human drug manufacturers to remind them of applicable legal requirements for notifying FDA of anticipated supply disruptions & to ask them to evaluate their entire supply chain, including active pharmaceuticals & other components manufactured in China.

2/29/20

Thread 2-- PPE:

1. We are currently not aware of specific widespread shortages of medical devices. [LINK TO SUPPLY CHAIN STATEMENT]
2. FDA has heard of increased demand & supply challenges of personal protective equipment (PPE)—gowns, gloves, surgical masks and/or respirator protective devices, or other equipment designed to protect the wearer from injury or the spread of infection or illness due to #COVID19
3. We are also aware of reports from @CDCgov & other partners of increased ordering of a range of human medical products as some healthcare facilities in the U.S. and preparing for potential future need if the outbreak were to become more serious.
4. We understand there are concerns about availability of PPE because of increased demand during the #COVID19 outbreak. This is not unexpected. If these supply challenges happen, we work closely with healthcare systems and local & regional health officials.

Week of 3/3/20

Thread 3—Blood/Biologics:

1. FDA is not aware of any cellular or gene therapies manufactured in China, and has identified no shortages of biologics as a result of supply chain disruptions from #COVID19 to report at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. The potential for transmission of #coronavirus by blood and blood components is unknown at this time; however, respiratory viruses, in general, are not known to be transmitted by blood transfusion.
3. There are no reported cases of transfusion-transmitted #COVID19.
4. The FDA has made information available to blood establishments and to establishments that manufacture human cells, tissues, or cellular or tissue-based products who may wish to consider additional donor screening measures in response to the #COVID19 outbreak.

3/2/20

Thread 4—Animal drugs:

1. There are 32 animal drug firms that make finished drugs in or source active pharmaceutical ingredients from China. @US_FDA has contacted all 32 firms & none have reported shortages as a result of #COVID19 at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. Although none of these 32 animal drug manufacturers have reported a shortage at this time, 6 firms have indicated that there have been disruptions in the supply chain that could soon lead to shortages. FDA is working with these firms to help identify interventions to mitigate any potential shortages.

Week of 3/3/20

Thread 5—Budget Proposal

1. The @US_FDA is using all our existing authorities to address #COVID19 and we welcome the opportunity to work with Congress to strengthen our #coronavirus response capabilities.
2. There are 4 specific proposals included in the President's FY 2021 budget that would better equip the agency to prevent or mitigate medical product shortages. Learn more about FDA's budget request: [LINK TO SUPPLY CHAIN STATEMENT]

@US_FDA Account

Individual Tweets

(b)(5)

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Incident Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

Center for Tobacco Products

Office of Health Communication and Education

U.S. Food and Drug Administration

Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/28/2020 4:19:46 PM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

I agree with Erika's comments and have no other suggestions. Thank you!

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 28, 2020 4:18 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

See edits below in blue.

For the first tweet,

(b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 28, 2020 4:02 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

See edits in red and in yellow below.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 28, 2020 3:55 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

For your approval OCC has cleared the following tweets on the supply chain statement.

Supply Chain Tweets

@SteveFDA Account

Individual tweets--- To be spread out

(b)(5)

3/1/20

2. See my update on how @US_FDA is monitoring the supply chain of FDA-regulated products and working to mitigate shortages during the #coronavirus outbreak: [LINK TO SUPPLY CHAIN STATEMENT]

(b)(5)

2/29/20

Thread 1—Drug shortage:

(b)(5)

2. The shortage is due to an issue with manufacturing an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients.
3. We are working with the manufacturer of this drug as well as other manufacturers to mitigate this shortage and will do everything possible to mitigate it. #COVID19
4. We have contacted over 180 human drug manufacturers to remind them of applicable legal requirements for notifying FDA of anticipated supply disruptions & to ask them to evaluate their entire supply chain, including active pharmaceuticals & other components manufactured in China.

2/29/20

Thread 2-- PPE:

1. We are currently not aware of specific widespread shortages of medical devices. [LINK TO SUPPLY CHAIN STATEMENT]
2. FDA has heard of increased demand & supply challenges of personal protective equipment (PPE)—gowns, gloves, surgical masks and/or respirator protective devices, or other equipment designed to protect the wearer from injury or the spread of infection or illness due to #COVID19

(b)(5)

4. We understand there are concerns about availability of PPE because of increased demand during the #COVID19 outbreak. This is not unexpected. If these supply challenges happen, we work closely with healthcare systems and local & regional health officials.

Week of 3/3/20

Thread 3—Blood/Biologics:

1. FDA is not aware of any cellular or gene therapies manufactured in China, and has identified no shortages of biologics as a result of supply chain disruptions from #COVID19 to report at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. The potential for transmission of #coronavirus by blood and blood components is unknown at this time; however, respiratory viruses, in general, are not known to be transmitted by blood transfusion.
3. There are no reported cases of transfusion-transmitted #COVID19.
4. The FDA has made information available to blood establishments and to establishments that manufacture human cells, tissues, or cellular or tissue-based products who may wish to consider additional donor screening measures in response to the #COVID19 outbreak.

3/2/20

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Week of 3/3/20

Thread 5—Budget Proposal

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2. There are 4 specific proposals included in the President’s FY 2021 budget that would better equip the agency to prevent or mitigate medical product shortages. Learn more about FDA’s budget request: [LINK TO SUPPLY CHAIN STATEMENT]

@US_FDA Account

Individual Tweets

2/29/20

(b)(5)

Abigail Capobianco, MA

Writer/Editor

Social Media Lead

Incident Management Group (IMG) Joint Information Center (JIC)

2019 Novel Coronavirus (COVID-19) IMG

Center for Tobacco Products

Office of Health Communication and Education

U.S. Food and Drug Administration

Tel: 240-402-4715

abigail.capobianco@fda.hhs.gov

<http://www.fda.gov/>



From: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]
Sent: 2/28/2020 5:38:46 PM
To: Kadlec, Robert (OS/ASPR/IO) [Robert.Kadlec@hhs.gov]; Ford-Barnes, Arwenithia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=38db99da9c0f4495b790adda00040fe7-HHS-Arwenithia]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Callahan, Victoria (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d5435dfac644077bd8590ebcaa98b57-HHS-Victori]; Moreno, Rafael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48adea165fff43a3911ac385c007e235-HHS-Rafael.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Rowell, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a36a105cf8004cf694126a14648dbac0-HHS-Scott.R]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Charrow, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12441403d18b42559a072c648988b55a-HHS-Robert.]; Grimm, Christi A (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f016a8789314dae984d5e4c5942161e-HHS-Christi]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; Op Divs [donald.rucker@hhs.govHHS]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Robertson, Lance (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e5ca0f7ed65142be8a4afc3665439486-HHS-Lance.R]; Khanna, Gopal (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9e1c88ded54049b23eff2bf35f16a1-HHS-Gopal.K]; Redfield, Robert R (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f1ab650905f424381ffbdd983419fcd-HHS-olx1-cd]; Verma, Seema (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2096b0c1e7f04e91897765d7ee0ac336-HHS-Seema.V]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Engels, Thomas J (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=016877d494194e198dd46952dd003393-HHS-TEngels]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]

CC: Sellers, Angela C (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8e728853b5a4be8ae1e3643837d92ae-HHS-Angela.]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Duncan, Blair B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cbe64717d9c44e18ac149ddf5b4b1630-HHS-Blair.D]; Arrieta, Jose (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=572d14811c0d46cea11922b5861bdd32-HHS-Jose.Ar]; Ashmore, Perryn (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a35672082a8649c98be98707d5774c6b-HHS-Perryn.]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Toedt, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d03bbf5205d341ae941dbb55ad243a29-HHS-Michael]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Kibunja, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=45afa7abc9804a0fae3498d8909905c4-HHS-Julia.K]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]

Subject: HHS COVID-19 Response - alignment of OPDIV/STAFDIV Efforts

Attachments: COVID-19 Health Care System Resilience_Alignment of HHS Efforts_External_Agenda (2020-03-03) Final.docx; Key_Themes_Challenges_Gaps_(2020-03-03) FINALv2.docx; COVID-19 Health Care System Resilience_Alignment of HHS Efforts Meeting Deck_2020_03_03_vF.pptx

Location: Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement | Washington, DC 20515

Start: 3/4/2020 9:00:00 AM

End: 3/4/2020 10:15:00 AM

Show Time As: Busy

Required Attendees: Ford-Barnes, Arwenitha (OS/ASPR/IO); Waters, Cicely (OS/ASPR/IO) (Cicely.Waters@hhs.gov); Shuy, Bryan (OS/ASPR/IO) (Bryan.Shuy@hhs.gov); Callahan, Victoria (OS/ASPR/IO) (CTR); Moreno, Rafael (OS/ASA/IOS) (Rafael.Moreno@hhs.gov); Trueman, Laura (HHS/IEA); Rowell, Scott (OS/ASA); Bird, Catherine (OS/OGC);

Moughalian, Jen (HHS/ASFR); Arbes, Sarah (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Giroir, Brett (HHS/OASH); Severino, Roger (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Charrow, Robert (HHS/OGC); Grimm, Christi A (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); Op Divs; Johnson, Lynn (ACF); Robertson, Lance (ACL); Khanna, Gopal (AHRQ/IOD); Redfield, Robert R. (CDC/OD); Verma, Seema (CMS/OA); Saxon, Bobby (CMS/CCIIO); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Engels, Thomas (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Krohmer, Jon (dot.gov)



COVID-19 Health
Care System Re...



Key_Themes_Ch...
FINALv2.docx



COVID-19 Health
Care System Re...

REMINDER: It is requested that you attend in person.

Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement

If you are unable to do so, please participate via the dial-in information below:

Number: (b)(6)
Access Code: (b)(6)

Dear ASPR Colleagues,

We are at a critical juncture in our nation's response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR's Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC's Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM**, at the O'Neill House Office Building for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to (b)(6) no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday's session.

- Your Designee(s) name, title, and contact information
- OPDIV/STAFFDIV name
- OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)
- OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)
- OPDIV/STAFFDIV key areas of concern or challenges identified to date
- OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts

We look forward to working with you on this critical effort to defend the nation's health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec
ASPR

POC:

Cicely L. Waters

Director, Office of External Affairs

Assistant Secretary for Preparedness and Response

U.S. Department of Health and Human Services

200 C St, SW Washington, D.C. 20201

(o) 202-205-0714 (m) **(b)(6)**

cicely.waters@hhs.gov

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/28/2020 6:29:23 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]; Kerns, Brook [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5102feea5171403a946818c3faf63bcb-Brook.Stone]
Subject: FW: WHO COVID-19 Situation Report #39 - 2/28/2020
Attachments: WHO Situation Report #39 COVID-19.pdf

Attached is the current WHO COVID-19 situation report.

-AN

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: [REDACTED] (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



**U.S. FOOD & DRUG
ADMINISTRATION**

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/28/2020 7:00:23 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
Subject: FYSA: FOR URGENT REVIEW: diagnostic guidance PR
Attachments: Diagnostic guidance_PR draft 628pm_clearance.docx

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Friday, February 28, 2020 6:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FOR URGENT REVIEW: diagnostic guidance PR

Hi all—

For your immediate review, here is the press release planning to issue tonight.

I spoke to Heidi and we also think we should send to Dr. Hahn now.

This is also in concurrent clearance. We will reconcile edits and flag any significant changes.

Thank you!

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/28/2020 7:02:51 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Minutes to send to Hahn with SitRep
Attachments: 2-28-20 COVID-19 AEG Meeting Notes.docx

From: Malais, Tanya <Tanya.Malais@fda.hhs.gov>
Sent: Friday, February 28, 2020 6:49 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: COVID-19 Agency Executive Group meeting moving forward.

RDAM Hinton.

Attached are my notes from today's AEG meeting. Some of the AEG members speak rather quickly, so I hope I was able to capture everything the Commissioner needs.

Tanya E. Malais
Documentation Unit Lead
COVID-2019 IMG
Office: 949-608-2984
Mobile: (b)(6)
Planning Section Email: 2019-nCoVFDAIMGPlanning@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you believe you have received this e-mail message in error, please e-mail the sender immediately at Tanya.Malais@fda.hhs.gov.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 28, 2020 5:57 PM
To: Malais, Tanya <Tanya.Malais@fda.hhs.gov>
Subject: RE: COVID-19 Agency Executive Group meeting moving forward.

Thanks Tanya. Perfect timing as Dr. Hahn would like notes from today's meeting to review prior to his meeting at the WH tomorrow.

From: Malais, Tanya <Tanya.Malais@fda.hhs.gov>
Sent: Friday, February 28, 2020 2:37 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: COVID-19 Agency Executive Group meeting moving forward.

RADM Hinton,

Thank you for forwarding the Mon. -Thur. COVID-19 AEG meeting invitation to me so that I can capture any action items for the IMG. I do not have the meeting invitation for the Friday 4:30 pm AEG meetings. Can you please forward the Friday AEG meeting invitation to me?

Thank you,
Tanya E. Malais
Documentation Unit Lead
COVID-2019 IMG

Office: 949-608-2984

Mobile: (b)(6)

Planning Section Email: 2019-nCoVFDAIMGPlanning@fda.hhs.gov

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From: Mair, Michael <Michael.Mair@fda.hhs.gov>

Sent: Friday, February 28, 2020 2:13 PM

To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>

Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.O'Callaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Bess, Demetrice <Demetrice.Bess@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Torres-Rivera, Sahra <Sahra.Torres-Rivera@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>

Subject: RE: COVID-19 Agency Executive Group meeting moving forward.

Apologies – AEG call is 4:30 PM today...

From: Mair, Michael

Sent: Friday, February 28, 2020 2:09 PM

To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Mayne, Susan <Susan.Mayne@fda.hhs.gov>; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>

Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Agler, Heather L

<Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Bess, Demetrice <Demetrice.Bess@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Torres-Rivera, Sahra <Sahra.Torres-Rivera@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>

Subject: COVID-19 Agency Executive Group meeting moving forward.

Hi. As discussed yesterday, for the daily AEG calls starting today and moving forward, the Commissioner would like to tick through the heck-list below. We will not be going over the SITREP, as everyone can read that. Instead this is intended to provide high-level updates on key issues and activities.

AEG representatives from Centers/Offices will be expected to report out on their respective areas. If you need additional people added to the call to support reporting out please advise.

Additionally as mentioned. After today's AEG call this afternoon @ 4:15 PM, these check-in will be scheduled for 9:15 – 9:30 AM daily.

Thx - m

AEG DAILY CHECKLIST

(b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/28/2020 7:33:23 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: FOR URGENT REVIEW: diagnostic guidance PR
Attachments: Diagnostic guidance_PR draft 628pm_clearance.docx

A few suggested edits for consideration if not too late.

Thanks,

Denise

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 28, 2020 6:52 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FOR URGENT REVIEW: diagnostic guidance PR

Hi all—

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I spoke to Heidi and we also think we should send to Dr. Hahn now.

This is also in concurrent clearance. We will reconcile edits and flag any significant changes.

Thank you!

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/28/2020 7:34:51 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
BCC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: FOR URGENT REVIEW: diagnostic guidance PR
Attachments: Diagnostic guidance_draft PR_730pm.docx

This version reads well and captures suggested edits.

Thanks,

Denise

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 28, 2020 7:32 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW: diagnostic guidance PR

OCC cleared PR— can we flip to Dr. Hahn asap?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 28, 2020 6:54 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: Re: FOR URGENT REVIEW: diagnostic guidance PR

No. Pls clear before sending to Hahn.

Sent from my iPhone

On Feb 28, 2020, at 6:51 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Hi all—

For your immediate review, here is the press release planning to issue tonight.

I spoke to Heidi and we also think we should send to Dr. Hahn now.

This is also in concurrent clearance. We will reconcile edits and flag any significant changes.

Thank you!

<Diagnostic guidance_PR draft 628pm_clearance.docx>

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 2/28/2020 9:38:52 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]
Subject: FW: FDA 2019-nCOV SITREP - 28 Feb 2020
Attachments: 26_2019-nCoV Outbreak_FDA SITREP_28 February 2020.docx

Today's FDA IMG COVID-19 Situation Report attached.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: _____(b)(6)_____

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 2/29/2020 3:11:34 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
CC: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Ruberry, Erin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eb9830932304426936396d5f70b4c04-Erin.Ruberr]
Subject: RE: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Thanks, Heidi!

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:10 PM
To: Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: Fwd: FOR YOUR REVIEW: tweets for today's action (EUA policy)

I haven't heard back from Commissioner yet on these but please let me know if you have any comments. I sent him text too.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:43:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <LauraCaliguiri@fda.hhs.gov>
Subject: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Dr. Hahn, here are the ones related to today's action. Yours are first 4 threads for @Steve. Thank you.

EUA Press Release Tweets
@Steve FDA Account

Thread 1

1. Today, as part of our continuous approach to addressing #COVID19, FDA issued a policy regarding certain laboratories using tests they develop & validate for #coronavirus faster in order to achieve more rapid testing capacity in the U.S. Learn more: <https://go.usa.gov/xddFR>
2. Effective immediately, FDA does not intend to object to the use of these diagnostic tests to detect #COVID19 while such laboratories are pursuing an EUA with FDA.

3. We believe this policy strikes the right balance during this public health emergency. We will continue to help to ensure sound science prior to clinical testing and follow-up with the critical independent review from FDA, while quickly expanding testing capabilities in the U.S.

4. We are not changing our standards for issuing EUAs. Today's action reflects our public health commitment to addressing critical public health needs and rapidly responding and adapting to this dynamic & evolving situation.

(b)(5)

(b)(5)

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 2/29/2020 3:12:27 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
CC: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Ruberry, Erin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eb9830932304426936396d5f70b4c04-Erin.Ruberr]
Subject: RE: FOR YOUR REVIEW: NY State EUA tweets

Thank you!

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:12 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: Fwd: FOR YOUR REVIEW: NY State EUA tweets

On NY announcement. Also haven't heard back from Commissioner in these so please let me know if you have any comment.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:41:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FOR YOUR REVIEW: NY State EUA tweets

Dr. Hahn, please review tweets on NY State EUA to go once EUA is issued. Other tweets for today's action coming your way separately.

NY STATE EUA TWEETS

(b)(5)

2. Coordination across all levels of government & with public health partners domestically & abroad is one of the reasons we remain optimistic about our country's preparedness & readiness despite the seriousness of the #COVID19 outbreak.

(b)(5)

4. We recognize that increased testing capabilities are a crucial component to coordinated government efforts in response to the #coronavirus outbreak & continue to work with EUA developers to hasten the development & accessibility of critical medical products like diagnostics.

(b)(5)

From: Kimberly, Brad [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08BC909ED76D49868A5FF92C3C70FB72-BRADLEY.KIM]
Sent: 2/29/2020 3:13:23 PM
To: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Capobianco, Abigail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=660b8e4204f74d4b912265b9c85613bd-Abigail.Cap]
Subject: RE: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Thank you. I have a little time here. He made a statement during the presser, which I recorded and just published on US_FDA. I retweeted from his account.

I still have three other posts to make before EUA goes out. Hoping to do that one after dinner.

Brad Kimberly

Director, Social Media

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel 240-402-1002 | Cell (b)(6)

brad.kimberly@fda.hhs.gov



From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:10 PM
To: Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: Fwd: FOR YOUR REVIEW: tweets for today's action (EUA policy)

I haven't heard back from Commissioner yet on these but please let me know if you have any comments. I sent him text too.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:43:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Dr. Hahn, here are the ones related to today's action. Yours are first 4 threads for @Steve. Thank you.

EUA Press Release Tweets

Thread 1

1. Today, as part of our continuous approach to addressing #COVID19, FDA issued a policy regarding certain laboratories using tests they develop & validate for #coronavirus faster in order to achieve more rapid testing capacity in the U.S. Learn more: <https://go.usa.gov/xddFR>
2. Effective immediately, FDA does not intend to object to the use of these diagnostic tests to detect #COVID19 while such laboratories are pursuing an EUA with FDA.
3. We believe this policy strikes the right balance during this public health emergency. We will continue to help to ensure sound science prior to clinical testing and follow-up with the critical independent review from FDA, while quickly expanding testing capabilities in the U.S.
4. We are not changing our standards for issuing EUAs. Today's action reflects our public health commitment to addressing critical public health needs and rapidly responding and adapting to this dynamic & evolving situation.

(b)(5)

(b)(5)

From: Capobianco, Abigail [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D4B912265B9C85613BD-ABIGAIL.CAP]
Sent: 2/29/2020 3:30:41 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
CC: Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Ruberry, Erin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6eb9830932304426936396d5f70b4c04-Erin.Ruberr]
Subject: RE: FOR YOUR REVIEW: NY State EUA tweets

Hi All,

CDRH just informed us that the target for approval is 7 p.m. tonight.

Thanks,
Abby

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:14 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: RE: FOR YOUR REVIEW: NY State EUA tweets

He's a WH so may respond shortly.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:12 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: Fwd: FOR YOUR REVIEW: NY State EUA tweets

On NY announcement. Also haven't heard back from Commissioner in these so please let me know if you have any comment.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:41:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: FOR YOUR REVIEW: NY State EUA tweets

Dr. Hahn, please review tweets on NY State EUA to go once EUA is issued. Other tweets for today's action coming your way separately.

NY STATE EUA TWEETS

(b)(5)

2. Coordination across all levels of government & with public health partners domestically & abroad is one of the reasons we remain optimistic about our country's preparedness & readiness despite the seriousness of the #COVID19 outbreak.

(b)(5)

4. We recognize that increased testing capabilities are a crucial component to coordinated government efforts in response to the #coronavirus outbreak & continue to work with EUA developers to hasten the development & accessibility of critical medical products like diagnostics.

(b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/29/2020 9:29:34 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]
Subject: RE: For signature: New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel
Attachments: NYS DOH EUA Diagnostic Panel HCP FS 02292020 FINAL.docx; NYS DOH EUA Diagnostic Panel Patient FS 02292020 FINAL.docx; NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf

Signed. Many thanks to all of you!

Best,

Denise

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Saturday, February 29, 2020 9:22 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: For signature: New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel

RADM Hinton,

For your signature (today) is the attached letter to issue an EUA for Wadsworth Center, NYSDOH's New York SARS-CoV-2 Real-time RT-PCR Diagnostic Panel.

These were cleared by CDRH (U.Scherf), OCC (C.Dennis), and OCET (M.Mair)

Also attached for reference are the two associated Fact Sheets.

If you have any question, please let me know.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 9:15:24 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: FW: COV-Supply Chain Coordination
Attachments: Supply Chain Options - N95 (PPE).pdf

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: March 2, 2020 at 9:11:41 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination

From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Saturday, February 29, 2020 9:41 PM
To: Eric.Rollison@cisa.dhs.gov; Glenn, Robert (b)(6); mark.fleming (b)(6); david.wade (b)(6); Polowczyk, John P RADM USN JS J4 (USA (b)(6) OBRIEN, Kristina M SES JS J4 (USA (b)(6); Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA <david.kless (b)(6) LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA (b)(6) Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA <Travis.Peck (b)(6) thomas.j.browning.mi (b)(6) william.t.viar.mi (b)(6) Brown, Christopher K. - OSHA <Brown.Christopher.K@dol.gov>; CoronavirusGlobalResponseCoordinationUnit (b)(6); GlasserJL (b)(6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) (b)(6) Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal (b)(6) Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA (b)(6) Nazak.Nikakhtar@trade.gov
Cc: DL NSC Resilience <(b)(6) Waterman, Paige E. EOP/OSTP (b)(6) Lin, Merry S. EOP/WHO (b)(6) Watson, Ian D. EOP/OSTP (b)(6) Davis, May M. EOP/WHO (b)(6) Honeycutt, Maria G. EOP/OSTP (b)(6) Sinclair, Michael R. EOP/NSC (b)(6) Hoelscher, Douglas L. EOP/WHO (b)(6) Goel, Andrea L. EOP/OMB (b)(6) Chafin, Kelly B. EOP/NSC (b)(6) Ferro, Phil J. EOP/NSC (b)(6) Fabina, Lauren C. EOP/NSC (b)(6) Rubini, Jeffrey H. EOP/NSC (b)(6) Butterfield, Nicholas W. EOP/WHO (b)(6) Abbott, Christopher J. EOP/WHO (b)(6) Troye, Olivia EOP/NSC (b)(6) Farquharson, Christine E. EOP/OMB (b)(6) Crozer, William F. EOP/WHO (b)(6) amie.kalsbeek@dot.gov; Bedan, Morgan E. EOP/WHO (b)(6) Cavanaugh, Brian J. EOP/NSC (b)(6) david.short@dot.gov; Krohmer, Jon (NHTSA) <jon.krohmer@dot.gov>; Holmes, Georgette (b)(6); Wilkinson, David (b)(6); Benjamin Carlson <Benjamin.Carlson@trade.gov>; Kroese, Daniel <(b)(6) Stevens, Kathleen E (b)(6) Tewell, Adam (OS) <Adam.Tewell@hhs.gov>; Elvander, Erika (OS) <Erika.Elvander@hhs.gov>;

Chandrasekera, Ruvani (OS) <Ruvani.Chandrasekera@hhs.gov>; Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Diana, Kevin (b)(6); Moudy, Robin (OS) <Robin.Moudy@hhs.gov>; Ayala, Ana (OS) <Ana.Ayala@hhs.gov>; Rausch, John T CIV OSD OUSD A-S (b)(6); Wurst, Nathan J CTR OSD OUSD A-S (USA (b)(6); Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA (b)(6); Garufi, Marc A. EOP/OMB (b)(6)

Subject: COV-Supply Chain Coordination

Dear Supply Chain Coordination Working Group (SSCWG),

Attached please find the document sent out on potential courses of action (COAs) for supply chain issues associated with N95 respirators. (b)(5)

(b)(5)

Thank you for your contributions towards developing this document, and I look forward to your continued engagement.

Seth.

Seth Jonas, PhD
Director for Critical Infrastructure
Director for Preparedness
National Security Council

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 12:34:04 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mignone, Alfred [Alfred.Mignone@fda.hhs.gov]
Subject: Immediate Action: Talking Points Request

Importance: High

Hi- just making sure this is being addressed so the information can be provided **before** 1:30 today. Patrizia provided talking points regarding chloroquine. Need the others ASAP. Please respond and let me know you have received this and are acting on it.

Thank you!

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, March 2, 2020 11:45 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Talking Points Request

Update: Dr. Hahn is joining a 12 PM Media Telebriefing, hosted by CDC. It will be Dr. Hahn and Dr. Messonnier to provide an update on COVID-19 response.

From: Olivarria, Frank
Sent: Monday, March 2, 2020 9:54 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Colin Rom (Colin.Rom@fda.hhs.gov) <Colin.Rom@fda.hhs.gov>; Anand Shah (Anand.Shah@fda.hhs.gov) <Anand.Shah@fda.hhs.gov>
Subject: Talking Points Request

Good morning Denise,

Starting a thread on items Dr. Hahn is requesting for today (taskforce meeting is at 3 PM, would be best to have any items by 1:30 PM for printing at his departure from WO, otherwise prior to 3 PM he can have them digitally for Task Force Mtg):

(b)(5)

(b)(5)

Please let me know if I can get any request calcification details from Dr. Hahn, or if we can be of any assistance in reaching out to collect these items prior to Dr. Hahn's taskforce meeting today.

Thank you,
Frank

Frank A. Olivarria
Management and Program Analyst
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Tel: 240-402-9882
Frank.Olivarria@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 2:00:56 PM
To: Lenihan, Keagan [Keagan.Lenihan@fda.hhs.gov]
Subject: FW: Supply Chain Updates - see highlight
Attachments: Supply Chain Options - N95 (PPE).pdf

We can discuss the highlighted information in yellow tomorrow morning and provide him with decision/input later?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 2, 2020 1:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Supply Chain Updates

Supply Chain Updates:

- **Requests for more detailed supply chain information:** We've been receiving requests from USG (HHS, DHS, DoD) and international (WHO, individual NBAs) partners for more detailed supply chain information, especially on the

(b)(5)

- **SNS:** Deploying some PPE (including some "expired" surgical masks) to Washington State to address supply challenges.

From: Raghuwanshi, Rakesh [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3084AEDBCB6049EDABCB11776F265A2A-RAKESH.RAGH]
Sent: 3/2/2020 2:57:08 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Letter from Representative Sheila Jackson Lee - Coronavirus
Attachments: 2000833.pdf

FYI only – letter from Rep. Jackson Lee to POTUS re: CoV response. Click the paperclip in left toolbar to view the letter.

Yeah, I know, the Congresswoman’s staff needs to proofread communications before sending them out.

From: Jackson, Valerie <Valerie.Jackson@fda.hhs.gov>
Sent: Monday, March 02, 2020 2:46 PM
To: Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: Letter from Representative Sheila Jones - Coronavirus

Good afternoon,

The attached document is being sent to you as an FYI.

Val

Valerie Jackson Watson
Senior Correspondence Analyst
FDA Executive Secretariat
301-796-4685
valerie.jackson@fda.hhs.gov

“TIMELESS TURTLE – STEADY, DEPENDABLE, STRONG”

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 4:43:26 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: For signature today: CDC EUA for certain respirators
Attachments: CDC EUA FFR Letter of Authorization 3-2-20 FINAL.pdf

Jennifer,

Attached is the signed document. Many thanks to all of you for your work on this.

Best,

Denise

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, March 2, 2020 4:35 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For signature today: CDC EUA for certain respirators

RADM Hinton,

For your signature (today) is the attached letter to issue an EUA to CDC for emergency use of certain respirators.

The EUA Declaration that was needed, has been signed by the Secretary already today.

The letter was cleared by CDRH (S.Schwartz), OCC (C.Dennis), and OCET (M.Mair) today.

For reference, CDC's request letter is attached and Appendix A referenced in the letter of authorization. Appendix B referenced in the letter of authorization is currently blank (and not attached), as authorized respirators will be added to it over time.

If you have any questions, then please let me know.

Thanks!

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov



From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/2/2020 5:54:44 PM
To: Janik, Heather [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117bc4d27d7b47ddbcb7f3d-Heather.Jan]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Lutter, Randall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=868b21db20e3456ab4e1b3109b56c23f-Randall.Lut]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
Subject: Science Magazine Article

Hi, I was sent this article by Randy. Based on the talking points I have seen though, (b)(5)

(b)(5)

Were they coordinating distribution of tests? Fortunately, it does note that things will get better. Could we 1.

(b)(5)

(b)(5)

The United States badly bungled coronavirus testing—but things may soon improve

By Jon Cohen Feb. 28, 2020, 5:45 PM

Speed is critical in the response to COVID-19. So why has the United States been so slow in its attempt to develop reliable diagnostic tests and use them widely?

The World Health Organization (WHO) has shipped testing kits to 57 countries. China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week; South Korea has tested 65,000 people so far. The U. S. Centers for Disease Control and Prevention (CDC),

in contrast, has done only 459 tests since the epidemic began. The rollout of a CDC-designed test kit to state and local labs has become a fiasco because it contained a faulty reagent. Labs around the country eager to test more suspected cases—and test them faster—have been unable to do so. No commercial or state labs have the approval to use their own tests.

In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID19 case without known links to an infected person.

The problems have led many to doubt that the official tally of 60 confirmed cases in the United States is accurate. The official tally of 60 confirmed cases in the United States is accurate. “There have been blunders, and there could be an underlying catastrophe that we don’t know about,” says epidemiologist Michael Mina, who helps run a microbiology testing lab at Brigham and Women’s Hospital. “It’s been very complicated and confusing for everyone with almost no clarity being provided by the CDC.”

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<https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/laboratory-guidance>

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Sent: Monday, March 2, 2020 6:16 PM
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Subject: FYSA - Signed EUA Letter of Authorization to CDC for Respirators
Attachments: CDC EUA FFR Letter of Authorization 3-2-20 FINAL.pdf

FYSA

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Sent: Monday, March 2, 2020 5:21 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

RADM Hinton,

Thank you for your help and support with this important effort!

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 2, 2020 at 5:18:15 PM EST
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Russ, Wanda <Wanda.Russ@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Thank you!

Denise

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Sent: Monday, March 2, 2020 4:59 PM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>

Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Adding Denise for awareness...

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Monday, March 02, 2020 4:57 PM

To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>

Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>

Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Hey folks—we are just waiting on VP's office to clear press release. Hopefully we can post soon.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Sent: Monday, March 02, 2020 4:51 PM

To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>

Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>

Subject: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Hello,

Please find attached the signed EUA Letter of Authorization (PDF), and Word Version.

An “umbrella” EUA was issued to CDC today for emergency use of certain respirators.

The issuance of the EUA is pursuant to HHS’s February 4th determination that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19 and the subsequent declaration from HHS earlier today that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak.

Congratulations to the team!

Jennifer

Jennifer Ross, PhD, JD

Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats

Office of the Chief Scientist / U.S. Food and Drug Administration

Tel 240-402-8155

Jennifer.Ross@fda.hhs.gov



Sent: 3/2/2020 7:56:33 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: NSC LOE2: Supply Chain Summary (due tonight)
Attachments: LOE2 NSC SC Background WG 3.2.20 DRAFT.pm.docx

Importance: High

No

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:15 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: NSC LOE2: Supply Chain Summary (due tonight)
Importance: High

Hi Keagan and Denise,

As mentioned earlier, attached for your review is the draft background document for LOE2 of the NSC Supply Chain Coordination WG. Do you have any edits or concerns? It's intended to very high level, in part to describe the complexities of the problem but also because other LOEs will be covering specific products (e.g., PPE, needles/syringes, investigational products).

Thanks,
Brooke

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 8:00:48 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: NSC LOE2: Supply Chain Summary (due tonight)
Attachments: LOE2 NSC SC Background WG 3.2.20 DRAFT.pm.docx
Importance: High

Reviewed – no edits or concerns from me.

Thank you!
Denise

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:15 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: NSC LOE2: Supply Chain Summary (due tonight)
Importance: High

Hi Keagan and Denise,

As mentioned earlier, attached for your review is the draft background document for LOE2 of the NSC Supply Chain Coordination WG. Do you have any edits or concerns? (b)(5)

(b)(5)

Thanks,
Brooke

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 8:09:17 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Action for 3/3 Covid19

We agree with your approach – thank you for crafting the remarks/TPs for review and clearance.

Best,
Denise

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 2, 2020 8:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Action for 3/3 Covid19

For tomorrow: I just received a readout on today's meeting and for tomorrow we need

Opening remarks for press conference [(b)(5)]
[(b)(5)]

[(b)(5)] Denise and Michael, are you comfortable with this approach? Please confirm and I will send email. Also, let me know if this is helpful or interrupts an existing process.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/2/2020 8:10:25 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Science Magazine Article

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:25 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Sidenote, there is another chain on this and Peter has been running to ground with WHO.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:21 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Yes, there are several publications that I'll be reaching out to, thanks for following up.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 02, 2020 7:13 PM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Extremely helpful. I neglected to include Stephanie on this chain. Stephanie and Laura

(b)(5)

(b)(5)

From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Date: March 2, 2020 at 7:06:18 PM EST

To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: RE: Science Magazine Article

Thanks again all.

Jeff said WHO confirmed that they have not made a test, shipped a test, or listed a test. The news stories are not accurate, so we should be clear about it.

Best,

Jennifer

Jennifer Brown Tomasello, MPA

Senior Policy Advisor

Center for Devices and Radiological Health

Office of Policy

U.S. Food and Drug Administration

Tel: 301-796-8924 - Cell: (b)(6)

jennifer.tomasello@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>

From: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

Sent: Monday, March 2, 2020 6:20 PM

To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

Subject: Re: Science Magazine Article

Looping in Tim and Jennifer.

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Date: March 2, 2020 at 6:12:00 PM EST

To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

Subject: Re: Science Magazine Article

+ Lauren

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>

Date: March 2, 2020 at 5:54:45 PM EST

To: Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>

Subject: Science Magazine Article

Hi, I was sent this article by Randy. Based on the talking points I have seen though, (b)(5)

(b)(5)

Were they coordinating distribution of tests? Fortunately, it does note that things will get better. Could we 1. (b)(5)

(b)(5)

The United States badly bungled coronavirus testing—but things may soon improve

By Jon Cohen Feb. 28, 2020, 5:45 PM

Speed is critical in the response to COVID-19. So why has the United States been so slow in its attempt to develop reliable diagnostic tests and use them widely?

The World Health Organization (WHO) has shipped testing kits to 57 countries. China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week; South Korea has tested 65,000 people so far. The U. S. Centers for Disease Control and Prevention (CDC), in contrast, has done only 459 tests since the epidemic began. The rollout of a CDC-designed test kit to state and local labs has become a fiasco because it contained a faulty reagent. Labs around the country eager to test more suspected cases—and test them faster—have been unable to do so. No commercial or state labs have the approval to use their own tests.

In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID19 case without known links to an infected person.

The problems have led many to doubt that the official tally of 60 confirmed cases in the United States is accurate. The official tally of 60 confirmed cases in the United States is accurate. “There have been blunders, and there could be an underlying catastrophe that we don’t know about,” says epidemiologist Michael Mina, who helps run a microbiology testing lab at Brigham and Women’s Hospital. “It’s been very complicated and confusing for everyone with almost no clarity being provided by the CDC.”

The situation may soon improve. State labs and commercial diagnostic developers hope to win approval from the Food and Drug Administration (FDA) for their own tests, and FDA and CDC on Wednesday agreed on a workaround for the faulty CDC kit—which has a problem that is not essential to its proper functioning—so that it can now be used by at least some of the state labs that have it.

But there’s widespread discontent with the way the system has worked. “The U.S. government has not appropriately prioritized diagnostic tests and supported the laboratory response network to the degree they should have been supported over the years,” says Luciana Borio, who in previous jobs had lead roles in responding to emerging threats at the National Security Council and FDA.

If a new disease emerges, CDC normally “gets the ball rolling” with diagnostics because it has the expertise and the biosafety laboratories to handle dangerous novel pathogens, says Borio, who now works for In-Q-Tel, a not-for-profit venture capital firm. Typically, there are few confirmed viral samples from patients at the outset, which researchers need to validate their tests, and CDC has the capability to grow the virus for this critical quality assurance step. Once the agency has a working test, that goes out to state labs. Then, in a third phase, commercial labs take over and either produce their own tests or scale-up the CDC one. “I would have hoped to see that third phase by now,” Borio says.

In the case of SARS-CoV-2, as the virus causing COVID-19 is officially known, CDC’s sluggishness was apparent 1 month ago. On 26 January, the agency held an unusual Sunday teleconference for the media to provide an update about the rapidly growing outbreak. There were then five cases in the United States, but the CDC lab in Atlanta was still the only one in the country able to test for the virus, and it repeatedly had backlogs. Asked why more labs weren’t able to do the tests, Nancy Messonnier, who then was leading CDC’s response, said it was a quality issue. “We hold ourselves to an incredibly high standard of precision in terms of laboratory testing,” Messonnier said. “We wouldn’t want to inadvertently make a mistake in patient care.”

CDC finally started to send kits to state and local health labs on 5 February. But on 12 February, it revealed that several labs had difficulty validating the test because of a problem with one of the reagents.

The key problem with the kits is what’s known as a negative control, says Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories (APHL). CDC’s test uses the polymerase chain reaction (PCR) assay to find tiny amounts of the SARS-CoV-2 genome in, say, a nose swab. To make sure a test is working properly, kits also include DNA unrelated to SARS-CoV-2. The assay should not react to this negative control, but the CDC reagents did at many, but not all, state labs. The labs where the negative control failed were not allowed to use the test; they have to continue to send their samples to Atlanta.

The declaration of a public health emergency ... limited the diagnostic capacity of this country. It’s insane.

Michael Mina, Brigham and Women’s Hospital

In principle, many hospital and academic labs around the country have the capability to carry out tests themselves. The PCR reaction uses so-called primers, short stretches of DNA, to find viral sequences. The CDC website posts the primers used in its test, and WHO publicly catalogs other primers and protocols, too.

Well-equipped state or local labs can use these—or come up with their own—to produce what are known as a “laboratory-developed tests” for in-house use.

But at the moment, they’re not allowed to do that without FDA approval. When the United States declared the outbreak a public health emergency on 31 January, a bureaucratic process kicked in that requires FDA’s “emergency use approval” for any tests. “The declaration of a public health emergency did exactly what it shouldn’t have. It limited the diagnostic capacity of this country,” Mina says. “It’s insane.”

On 24 February, APHL asked FDA Commissioner Stephen Hahn for “enforcement discretion” to sidestep the emergency process and allow APHL members labs to use their own tests. On 26 February, Hahn replied that the CDC test could be modified to use just the primers that specifically detect SARS-CoV-2, essentially ignoring the faulty portion of the kits. FDA, in other words, would look the other way to make more widespread testing possible.

CDC has notified labs of FDA’s decision in a letter, but the agency must still file an emergency use authorization with FDA for the protocol change. Once it does, it won’t take long, Hahn promised in his letter to APHL: “FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation.”

In New York, the State Department of Health has designed its own test based on the CDC protocol and plans to seek emergency use authorization.

CDC provided an update about the situation in an email but did not respond to *Science*’s request for an interview with a scientist to discuss the details of the problem. Mina stresses he has great respect for CDC’s competence overall, but says, “There’s no good explanation for what’s going on here.”

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/3/2020 10:08:17 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: FYSA: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

(b)(5)

will keep you updated in real time.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:06 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: FYSA: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Thank you Denise

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 9:41 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FYSA: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 9:37 AM
To: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

<https://www.governor.ny.gov/news/novel-coronavirus-briefing-governor-cuomo-announces-state-partnering-hospitals-expand-novel>

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Sent: 3/3/2020 10:09:09 AM
To: Sapsford, Kim E [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=564aa450b77d455b922015ece2101829-KIS]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Scherf, Uwe [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b184b713fc4d4edc84d1aed078aafec7-UXS]; Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Both – please and thank you.

From: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:08 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Marcy or Liz? – in the letter “Testing is limited to the Wadsworth Center, New York State Department of Public Health (“Wadsworth Center NYSDOH”), and the New York City Department of Health and Mental Hygiene, Public Health Laboratories (“NYC DOHMH/PHL”)”

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead

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Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov



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<https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E>.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Sent: Tuesday, March 03, 2020 10:07 AM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Liz for engagement – thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 10:05 AM

To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: Re: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Let me know pls.

Sent from my iPhone

On Mar 3, 2020, at 9:45 AM, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov> wrote:

Are they allowed to do that – (b)(5)

Kim Sapsford-Medintz, Ph.D.

MCM EUA Team Lead

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<image007.png>

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<image011.jpg>

<image012.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
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From: Mair, Michael <Michael.Mair@fda.hhs.gov>

Sent: Tuesday, March 03, 2020 9:37 AM

To: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

<https://www.governor.ny.gov/news/novel-coronavirus-briefing-governor-cuomo-announces-state-partnering-hospitals-expand-novel>

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From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/3/2020 10:36:56 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York
Attachments: NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf

+Carly

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

BLUF: Under the EUA, the authorized labs were just the two labs (Wadsworth and NYC DOHMH/PHL) and there was no provision to add more authorized laboratories (b)(5)

(b)(5)

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:28 AM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

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(b)(5)

Thanks,

Jennifer

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:15 AM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Jennifer...

(b)(5)

(b)(5)

From: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 10:08 AM

To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

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Sent: Tuesday, March 3, 2020 10:05 AM

To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

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Sent from my iPhone

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Are they allowed to do that – (b)(5)

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<image010.jpg>

<image011.jpg>

<image012.jpg>

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Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

<https://www.governor.ny.gov/news/novel-coronavirus-briefing-governor-cuomo-announces-state-partnering-hospitals-expand-novel>

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/3/2020 10:55:11 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: IMG Documents FYSA
Attachments: 03-03-2020 Novel Corona Virus OpTempo.pptx; COVID-19 FDA Meetings_03_2-6_2020.xlsx; 2020-02-25-Organizational-Chart-2019-nCoV-IMG (3).pptx

Per our discussion yesterday.

Thank you,
Denise

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 3/3/2020 12:19:05 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FOR CLEARANCE: TP for Press Conference
Attachments: 20200303HahnTPsforWHTF_OCCcleared_clean.docx

The attached talking points are cleared by JIC/IMG and OCC. Thank you.

-April

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:52 AM
To: Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: TP for Press Conference

Good morning-thanks for your help. (b)(5)
(b)(5). Then please clear this version. This needs to be cleared for Hahn at 1.

From: Finnen, April <April.Finnen@fda.hhs.gov>
Date: March 3, 2020 at 7:18:47 AM EST
To: Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: TP for Press Conference

Happy to help. What time is the press conference today (i.e., when does this need to be cleared by)? And is the version Michael sent the one you want IMG-cleared?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, March 2, 2020 10:46 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: TP for Press Conference

Hi – some suggestions attached – use whatever works.

Copying April who can help push through JIC clearance once u have final version u want cleared. Thx - m

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 2, 2020 9:44 PM

To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: TP for Press Conference

Thanks Stephanie and Carly. Just a minor suggested edit from me. Michael will review shortly.

Best,

Denise

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 2, 2020 9:25 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: FOR CLEARANCE: TP for Press Conference

Hi, attached are talking points for tomorrow's press conference that Stephanie and I drafted. Wanted to let you both review first and then would appreciate your help with clearance. Is there someone that does clearance at the IMG?

(b)(5)

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/3/2020 1:15:30 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: so far material from today
Attachments: 20200303HahnTPsforWHTF_OCCcleared_clean.docx; WHTF Briefing 03.03.2020 COMPILED.docx

I am on a call now but I wanted to flag these materials for you both. I will let you know when I hear back from jeff (should be by 1:30). Once I finalize these I think we should save them in sharepoint so we can use as base for tomorrow's materials.

TP for Press Conference (from April, cleared JIC/IMG)



20200303HahnT...

Background document for Dr. Hahn's briefing this afternoon
(still pending clearance from Shuren/CDRH) Highlighted new information.



WHTF Briefing
03.03.2020 COM..

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/3/2020 2:10:11 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: NYTimes

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 2:07 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 2:00 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>;

Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: NYTimes

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PRE-DECISIONAL, CONFIDENTIAL

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
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(b)(5)

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Stephanie did I miss anything?

Trump Administration Sends Mixed Signals on Coronavirus Testing

The Food and Drug Administration chief said Tuesday that enough tests would be on hand this week for a million virus tests, but the actual number of tests administered will likely be far lower.



“I don’t think that we are going to get out of this completely unscathed,” Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, said. Credit...Anna Moneymaker/The New York Times



By Noah Weiland and Emily Cochrane

• March 3, 2020, 12:43 p.m. ET

WASHINGTON — The Trump administration sent mixed signals on Tuesday about how quickly testing for the coronavirus would ramp up, stressing that close to a million coronavirus tests should be available this week but also that the number of tests to be administered remained unknown.

Dr. Stephen Hahn, the commissioner of the Food and Drug Administration, said at a Senate hearing that the Centers for Disease Control and Prevention was working with a private manufacturer to drastically increase the testing capacity of laboratories across the nation.

“Our expectation in talking to the company that is scaling this up is that we should have the capacity by the end of the week to have kits available to the laboratories to perform about a million tests,” he said.

White House officials, however, stressed that the number of tests actually administered could be considerably lower. When Dr. Hahn was asked to clarify, he said that he was hearing from private manufacturers that 2,500 test kits could be available by the end of the week, with each kit capable of 500 tests.

“This is a dynamic process,” Dr. Hahn said. “Every day we’re hearing from additional manufacturers.”

The F.D.A. has said that Dr. Hahn was taking into account the anticipated production of test kits by Integrated DNA Technologies, which is now selling kits to the federal government and other buyers. But that would not increase the capacity of individual labs to perform the tests.

The confusion typified the struggle by the Trump administration to project confidence and progress without misleading the public about the virus's spread. New infections in Westchester County, N.Y., San Mateo County, Calif., and Fulton County, Ga., since Monday evening made clear coronavirus was spreading in the sprawl of America's largest urban centers and was no longer tethered to international travelers. In the United States, there have been at least 105 cases of coronavirus confirmed by lab tests as of Tuesday morning, and worldwide infections topped 92,200.

Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, told Politico that Americans should expect the outbreak to worsen.

"I don't think that we are going to get out of this completely unscathed," he said. "I think that this is going to be one of those things we look back on and say, 'boy, that was bad.'"

Get an informed guide to the global outbreak with our daily **coronavirus** newsletter.

The number of tests that will be administered in the coming days could be substantially lower than the projection Dr. Hahn had offered. A spokesman for the Department of Health and Human Services said Monday that public health labs currently can test 15,000 people, and could test up to 75,000 by the end of the week, numbers that fall well short of what Dr. Hahn suggested could result from private manufacturing.

The Association of Public Health Laboratories, which represents state and local government laboratories around the country, has said that its labs would be able to conduct about 10,000 tests a day when all of its 100 members that can perform testing are running. Scott Becker, the executive director of the lab association, said Monday that labs can run about 100 tests per day. As of Monday, he said fewer than half of those labs were able to do so.

Dr. Fauci told Politico that he would be truthful in his public pronouncements, even as President Trump sought to minimize the virus's impact.

"You should never destroy your own credibility. And you don't want to go to war with a president," Dr. Fauci told Politico in an interview Friday. "But you got to walk the fine balance of making sure you continue to tell the truth."

At several hearings across Capitol Hill on Tuesday morning, other Trump administration officials spoke to different elements of the federal response.

Chad Wolf, the acting secretary of the Department of Homeland Security, told the House Homeland Security Committee on Tuesday that he ordered a department field office in King County, Wash., to close for 14 days after learning that one of its employees visited a relative at Life Care Center in Kirkland, Wash., a nursing home where four of the six Americans who have died of the virus lived.

Mr. Wolf said he also directed employees at the field office to quarantine themselves for 14 days.

The employee visited Life Care Center before it became a focal point of the outbreak, Mr. Wolf said.

"This employee embodied leading by example," Mr. Wolf said.

In another hearing, Steven Mnuchin, the Treasury secretary, said that the Trump administration is working with other countries to do everything possible to curb the spread of the virus and to limit damage to the global economy.

"The administration is closely monitoring the coronavirus and its effect on public health as well as any effects on supply chains, markets and the broader economy," Mr. Mnuchin said, adding that the White House wanted to work closely with Congress for emergency funding.

Representative Richard Neal of Massachusetts, the chairman of the House Ways and Means Committee, told Mr. Mnuchin that any stimulus package should be centered around infrastructure investment rather than additional tax cuts.

"If there's a need to stimulate the economy as a result of the coronavirus, I'm sure that infrastructure is a priority of the president," Mr. Mnuchin said.

Mr. Mnuchin said the Trump administration was not considering rolling back or suspending its tariffs on Chinese imports to mitigate the economic effects of the coronavirus.

He said that the Treasury Department had set up a group to begin looking at tax measures that the Trump administration could take to provide relief to small and medium-sized businesses. He said that the White House could present proposals to Congress for such action if needed.

As the Trump administration officials testified, lawmakers were working on an emergency spending bill, hoping to pass it before a mid-March break. The legislation, which could be unveiled Tuesday, is expected to be worth \$7 billion to \$8 billion.

The package, which has been quickly negotiated over the past few days, is expected to be significantly larger than what the White House initially proposed eight days ago: \$1.25 billion in new funds, paired with a transfer of existing funds from other health programs.

Zolan Kanno-Youngs and Alan Rappeport contributed reporting from Washington, Katie Thomas from Chicago and Knavul Sheikh from New York.

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Sent: Tuesday, March 3, 2020 12:31 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: NYTimes

<https://www.nytimes.com/2020/03/03/health/coronavirus-tests-fda.html>

Carly – Can we pass this to OEA / CDRH

(b)(5)

Anand

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 3/3/2020 2:18:49 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
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Keagan's point is where I was headed with my earlier comment – need to make it understandable to the public, and I think Keagan said it well

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 2:16 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Re: NYTimes

(b)(5)

Sent from my iPhone

On Mar 3, 2020, at 2:07 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

(b)(5)

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From: Shah, Anand <Anand.Shah@fda.hhs.gov>

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<image001.jpg>

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<image002.png>

<image003.png>

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Carly – Can we pass this to OEA / CDRH

(b)(5)

Anand

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Sent: 3/3/2020 9:00:44 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: Update w/ test #s from this morning

Looping in others for situational awareness.

From Jeff:

(b)(4) (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 6:18 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: RE: Update w/ test #s from this morning

Just need you to get an answer (b)(5) Don't worry about the rest, thanks.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 6:17 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Update w/ test #s from this morning

I pinged Jeff but does Giroir's email mean (b)(5) Wasnt sure what be with them means

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 3, 2020 at 5:38:17 PM EST
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: Update w/ test #s from this morning

I need to know why we

(b)(5)

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 3/4/2020 6:46:05 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: 3/3 ACTION ITEMS-PLEASE REVIEW THIS DRAFT

Hi Carly. I have asked that you be given access to SharePoint. I've loaded these docs in [a folder for White House Briefings](#), which you are welcome to use going forward. Any time you need talking points routed for JIC/IMG and OCC review, please let me know and the JIC can assist. I'm working on identifying additional team members who can help monitor for and cover these late evening requests if things need to be routed immediately. The JIC members work closely with their IMG operations counterparts (e.g., CDRH for devices), so we can help you get these things in front of the right people to review quickly. We just need to know when you need the OCC-cleared version back. Happy to discuss our process, and work with you to streamline—just let me know.

Thanks,
April

p.s. We have an OCC-cleared talking points list that is updated almost daily now with the latest. You can find it in the SP [Talking Points](#) folder.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 9:53 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: RE: 3/3 ACTION ITEMS-PLEASE REVIEW THIS DRAFT

Hello! Only read out on press gaggle and meeting this evening is a request for talking points for VP meeting with diagnostic manufacturers (which they set up today). I drafted and sent to CDRH for clearance.

Did we send decision memo to Keagan and commissioner re: travel? Also updated status of projects below: please let me know what I am missing. Thank you.

From: McWilliams, Carly
Sent: Tuesday, March 3, 2020 5:13 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: 3/3 ACTION ITEMS-PLEASE REVIEW THIS DRAFT

(b)(6)

I created a working list of all items we are working on. Could you both review and add items I may be missing. My goal is to send this out tonight with action items from the WHTF meeting.

(b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 6:58:08 AM
To: Roth, Kristian [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e5477cd3ec4cc6856a1e40358afbb0-Kristian.Ro]
Subject: Re: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Thank you for Kristian - this was meant for Lauren Roth and I sent it to her following your email.

Have a great day!

Denise

From: Roth, Kristian <Kristian.Roth@fda.hhs.gov>
Date: March 4, 2020 at 6:30:39 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Dear Denise,
The email below was sent to me by mistake.

Kris

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 8:21 PM
To: Roth, Kristian <Kristian.Roth@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Lauren,

I believe Laura Wolf is the right person and directly engages with interagency partners. She's very responsive – her POC information is below:

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov.gov
Desk: 202-260-0666

(b)(6)

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 8:13 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Michael and Denise,

We have received from questions from OMB (see attached) on our "plan" for issuing the CDRH enforcement discretion guidance. But, some of them (most of them) are really questions for CMS or others in the Department. Is there someone at HHS that could help identify the right POCs to respond? Happy to discuss if that's easier. Unfortunately, I think we're trying to get back to OIRA by tomorrow, so I need to find the right person asap. Keagan suggested I ask if you could direct me.

Thanks,
Lauren

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 7:22 PM

To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>

Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

My thoughts, see attached.

Best,
Tim

Timothy T. Stenzel, MD, PhD

*Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality*

**Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov**

Jennifer Campbell
Administrative Assistant

*OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality*

*CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov*

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?ID=19000&S=E>

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>

Sent: Tuesday, March 3, 2020 7:11 PM

To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>

Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

All,

We received the following email from OIRA, with questions on our original "plan" document. My best guess is that these questions are stragglers (given that they are reflected on the plan and not the guidance itself), but HHS has asked us to respond by tomorrow.

(b)(5)

Let me know if you would like to discuss.

Thanks,
Lauren

From: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Sent: Tuesday, March 3, 2020 1:06 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; OC OPPB OP RPMS <OC●PPB●PRPMS@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Lauren,

Please find attached some follow-up questions from the Medicare team of OIRA. If FDA could provide bubble responses on the attached by tomorrow, that would be great.

Thank you

From: Hirsch, Quinn N. EOP/OMB (b)(6)
Sent: Tuesday, March 3, 2020 12:57 PM
To: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Cc: Fischbach, Aaron (OS/IOS) <Aaron.Fischbach@hhs.gov>
Subject: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Kat,

(b)(5)

Thanks,
Q

Quinn N. Hirsch, MPH

(b)(6)

(she/her/hers)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 9:45:11 AM
To: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: FW: TWEETS for REVIEW: HELP Testimony // Feed Your Mind

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:46 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: TWEETS for REVIEW: HELP Testimony // Feed Your Mind

Look good. Keagan, (b)(5)
S

Sent from my iPad

On Mar 4, 2020, at 8:25 AM, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov> wrote:

Good morning... two threads for your review this AM. Thanks! --Brad

===

HELP Testimony

1. Yesterday, I had the opportunity to update the senate HELP committee about FDA's latest actions addressing #COVID19 outbreak, including the availability of diagnostics as industry ramps up production. **[VIDEO CLIP]**
2. In addition to CDC continuing distribution of their test, we have heard from a commercial manufacturer that they will be ramping up production of CDC's authorized test & produce more than 1 million tests by the end of this week. <https://www.fda.gov/news-events/congressional-testimony/hearing-emerging-disease-threat-how-us-responding-covid-19-novel-coronavirus-03032020>
3. Going forward, this manufacturer expects to produce significantly more tests.

Feed Your Mind

1. Excited to launch #FeedYourMind today with @USDA & @EPA, to help you better understand everyday foods created with genetic engineering (also called GMOs). **[hyperlink][image]**

2. Genetic engineering has created new plants that are resistant to insects and diseases, led to products with improved nutritional profiles & certain produce that don't brown/bruise as easily.

Brad Kimberly

Director, Social Media

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel 240-402-1002

brad.kimberly@fda.hhs.gov

(b)(6)

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 10:13:07 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: IMG Ask
Attachments: COVID-19 Health Care System Resilience_Alignment of HHS Efforts Meeting Deck_2020_03_03_vF.pptx; Key_Themes_Challenges_Gaps_(2020-03-03) FINALv2.docx; COVID-19 Health Care System Resilience_Alignment of HHS Efforts_External_Agenda (2020-03-03) Final.docx

Hi Michael,

Please work to identify high level FDA needs to communicate to the HHS COVID19 Response-Alignment of OPDIV/STAFDIV Efforts (One pager – bulleted- bucketed). We can also highlight areas in which we are already working with our interagency partners { (b)(5) }

Thanks,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 10:57:43 AM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: IMG Documents for reference
Attachments: 03-03-2020 Novel Corona Virus OpTempo.pptx; COVID-19 FDA Meetings_03_2-6_2020.xlsx; 2020-02-25-Organizational-Chart-2019-nCoV-IMG (3).pptx; 2019-nCoV IMG2.pptx

Good morning,

Attached please find the IMG Daily OpTempo, a combined meetings list, and IMG organizational structure, TF and distribution lists for reference.

We'll need to revise to capture the OC-Commissioner Comms component within the AEG.

Thank you,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 10:59:46 AM
To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: Print please
Attachments: 28_2019-nCoV Outbreak_FDA SITREP_3 March 2020.docx

Hi,

Attached for your situational awareness is the 03 March FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Many thanks for your continued support. -Michael

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/4/2020 11:29:30 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: TP FOR VP at test developer roundtable
Attachments: Hahn_diagnostic-roundtable_3.4.20_cleared.docx

Cleaned up attached.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 11:26 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: TP FOR VP at test developer roundtable

Can you clean up and get to Frank/Colin for him? He is leaving in a few mins.

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 11:18 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: TP FOR VP at test developer roundtable

Thanks Stephanie, suggestions from OCC attached – please reach out to Claire and Marcy if you have questions or concerns.

Thanks,
Dinesh

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 10:50 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: TP FOR VP at test developer roundtable

Hi—

We may need some brief opening remarks for Dr. Hahn at this roundtable. Do these look ok?

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Wednesday, March 04, 2020 9:35 AM

To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Subject: RE: TP FOR VP at test developer roundtable

(b)(5)

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>

Sent: Wednesday, March 4, 2020 8:35 AM

To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Subject: TP FOR VP at test developer roundtable

Good Morning,

(b)(5)

We need to send in this morning, it is possible to get these cleared by 10am?

(b)(5)

Thank you in advance! As a heads up, we were also asked to look at information about (b)(5) and discuss at the 4pm VP meeting so cder is developing talking points and I will send for clearance as soon as I receive them.

Appreciate all of your help!

Carly

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/4/2020 2:57:02 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: urgent or i have to send
Attachments: WHTF Briefing 03.04.2020 COMPILED.docx
Importance: High

Can you please review asap. Highlighted is new. I need to get to commissioner asap

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/4/2020 4:31:29 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: FW: TPs for today
Attachments: 2020.03.04_WHTF_TPs_v3.docx

From: Caccomo, Stephanie
Sent: Wednesday, March 4, 2020 4:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: TPs for today

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 7:28:13 PM
To: O'Shaughnessy, Jacqueline A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fcc0bbfc81941e497313b309196f28b-OSHAUGHNESS]
Subject: FW: COVID19 CONPLAN
Attachments: 20200304FDA_COVID19 CONPLAN_March_2020 V1.2.2docx.docx

From: Carter, Lionel <Lionel.Carter@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 6:45 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Koerner, Harold <Harold.Koerner@fda.hhs.gov>
Subject: COVID19 CONPLAN

Hello Admiral Hinton

Here is the Coronavirus Disease 2019 Outbreak (COVID19) Concept of Operations Plan. (b)(5)
(b)(5) We will probably need a technical

editor to run through it quickly also, however the text has been updated based on the reviews that were able to be undertaken today by the IMG. I'd recommend that it be sent through the Offices/Centers (AEG) for a scrub and then we can finalize. It is also recommended we conduct that review via a SharePoint site. However if you prefer a different method we are certainly amenable to it. Apologies for the delay, however we wanted to make sure to address all comments.

V/r

Lionel Carter Acting Director
Office of Security and Emergency Management
10903 New Hampshire Avenue, WO32- RM1353
Silver Spring, MD 20993
PH:301-796-2796 | Mobile: (b)(6)
Lionel.Carter@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 8:05:55 PM
To: Orsega, Susan (OS/OASH) [Susan.Orsega@hhs.gov]
CC: Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Good evening RADM Orsega,

I believe this has already been addressed

(b)(5)

(b)(5)

I'm happy to speak by phone at any time to discuss details

(b)(6)

V/r,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

From: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Sent: Wednesday, March 4, 2020 5:59 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Please advise.

Regards,

Susan M. Orsega
Rear Admiral, Commissioned Corps Headquarters Director
United States Public Health Service
Office of the Surgeon General /US Department of Health and Human Services

(b)(6)

Email: susan.orsega@hhs.gov

From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:22 PM
To: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo (FDA/CDER) <Khushboo.Sharma@fda.hhs.gov>

Subject: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Hello Ma'am,

I am reaching out on behalf of leadership in Office of New Drugs (OND) in CDER/FDA. We have received a CC officer request from high up in the US Government that we urgently need to discuss with you.

Would you please call Khushboo Sharma's office at 301-796-1270 as soon as you are able? Ms. Sharma is OND's Deputy Office Director for Operations.

Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service

Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience

Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-1160
Jacqueline.ware@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 8:11:39 PM
To: Nabakowski, Andrei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c8bcecc310c4e45a5012d47d40886e1-NABAKOWSKIA]; Goldman, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]; Kerns, Brook [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5102feea5171403a946818c3faf63bcb-Brook.Stone]
Subject: RE: Update; (b)(5) RE: URGENT:
Coronavirus request from FDA/CDER/OND)

Absolutely!

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:09 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: RE: Update; (b)(5) RE: URGENT:
Coronavirus request from FDA/CDER/OND)

Exactly. I spoke with the OND Deputy Director for Operations and she said the (b)(5)

(b)(5)

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: (b)(6)



From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Sent: Wednesday, March 4, 2020 7:59 PM

To: Goldman, David <David.Goldman@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Kerns, Brook <Brook.Kerns@fda.hhs.gov>

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Subject: Re: Update (b)(5) RE: URGENT:
Coronavirus request from FDA/CDER/OND)

Thank you—do we know why the name-request?

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To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Goldman, David <David.Goldman@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>, Kerns, Brook <Brook.Kerns@fda.hhs.gov>

Subject: FW: Update (b)(5) RE: URGENT:
Coronavirus request from FDA/CDER/OND)
Importance: High

Passing the FDA PHS leadership for awareness (b)(5)

(b)(5)

(b)(5)

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Andrei Nabakowski, PharmD

Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
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FCCA | FDA Commissioned Corps Affairs
OTS | Office of Talent Solutions



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To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Logistics <2019-nCoVFDAIMGLogistics@fda.hhs.gov>
Subject: Update: (b)(5) (RE: URGENT: Coronavirus request from FDA/CDER/OND)
Importance: High

Update: I spoke directly with Khushboo Sharma [CDER OND Deputy Director for Operations] who confirmed that a

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Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>;
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Sent: Wednesday, March 4, 2020 5:40 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>;
FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Michael and Tom,

Please see the “urgent” request below from CDER.

Russell Zablan
Emergency Coordinator
Office of Emergency Operations (OEO)
Office of Emergency Management (OEM)
U.S. Food and Drug Administration
Duty Station: Atlanta, GA
Office: 404-253-2264
Blackberry: (b)(6)
Email: russell.zablan@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:36 PM
To: FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

From: Ware, Jacqueline H
Sent: Wednesday, March 04, 2020 5:22 PM
To: Orsega, Susan (OS) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
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From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/4/2020 8:46:03 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: Fwd: Briefings Tomorrow
Attachments: image001.png; ATT00001.htm; Reactive Responses for Dr. Shah - 3.4.20 - LP additions.docx; ATT00002.htm; AS House Senate Update 3.4.20jbt.eh_OCC.docx; ATT00003.htm

Talking points

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Date: March 4, 2020 at 8:41:46 PM EST
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Fwd: Briefings Tomorrow

Begin forwarded message:

From: "Tantillo, Andrew" <Andrew.Tantillo@fda.hhs.gov>
Date: March 4, 2020 at 6:21:00 PM EST
To: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Cc: "Gross, Karas" <Karas.Gross@fda.hhs.gov>, "Paulos, Lauren" <Lauren.Paulos@fda.hhs.gov>
Subject: RE: Briefings Tomorrow

Apologies, omitted a bullet in the reactive. Updated version attached here.

From: Tantillo, Andrew
Sent: Wednesday, March 4, 2020 6:19 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Gross, Karas <Karas.Gross@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: Briefings Tomorrow

Dr. Shah-

Attached are your proposed talking points for a statement, and some responses in the event you are asked about the topics we discussed today.

The first briefing is at 8:00am in room 419A of the Dirksen Senate Office Building. You will ride over from Humphrey in the ASL car with your fellow presenters. If for some reason you do not, it is a short cab ride from HHS, and you can enter Dirksen via the door at First St. & Constitution St., NE and proceed to the 4th floor. Either way Lauren Paulos and I will meet you outside the briefing room.

The second briefing is at 9:15am in the Capitol Visitor Center Auditorium. We will walk over with the HHS party.

Thank you for your willingness to do this on short notice. My cell number is (b)(6) if anything comes up or you need anything.

Andrew Tantillo

Deputy Director

Office of Legislation
U.S. Food and Drug Administration

● 301-796-8919 M: (b)(6)

andrew.tantillo@fda.hhs.gov

From: Goldman, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7A9C6C3E900B4771876C53FA24C1172B-DAVID.GOLDM]
Sent: 3/4/2020 8:51:04 PM
To: Nabakowski, Andrei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c8bcecc310c4e45a5012d47d40886e1-NABAKOWSKIA]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]; Tarver, Darian B. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Anderson, Randy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA]; Kerns, Brook [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5102feea5171403a946818c3faf63bcb-Brook.Stone]
Subject: RE: Update: (b)(5) (RE: URGENT: Coronavirus request from FDA/CDER/OND)

Thanks for this info. Indeed an honor to be asked to contribute in this way.

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Date: March 4, 2020 at 8:08:31 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Goldman, David <David.Goldman@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>, Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: RE: Update: (b)(5) to CDER/OND (RE: URGENT: Coronavirus request from FDA/CDER/OND)

Exactly. I spoke with the OND Deputy Director for Operations and she said the (b)(5)

(b)(5)

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
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FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
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Importance: High

Passing the FDA PHS leadership for awareness:

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FDA U.S. FOOD & DRUG
ADMINISTRATION

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Emergency Coordinator
Office of Emergency Operations (OEO)
Office of Emergency Management (OEM)
U.S. Food and Drug Administration
Duty Station: Atlanta, GA
Office: 404-253-2264
Blackberry: (b)(6)
Email: russell.zablan@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 8:54:25 PM
To: Sharma, Khushboo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0c8e73a04e14d15bb313bf0bc66ded6-SHARMAKH]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63ed25c8067c4b838dbb689460ce0486-HHS-Susan.O]; Ware, Jacqueline H [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ff5ecea6fb2c401096888ec836483d9a-WAREJ]
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Noted – thank you, Khushboo.

From: Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:53 PM
To: Orsega, Susan (OS) <Susan.Orsega@hhs.gov>; Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Hello,

We had a [redacted] (b)(5)
[redacted] (b)(5)

I appreciate all your help.

Khushboo Sharma, MBA, RAC
Deputy Office Director of Operations
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-1270 Cell: [redacted] (b)(6)
Khushboo.sharma@fda.hhs.gov



From: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Sent: Wednesday, March 4, 2020 8:49 PM
To: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Good evening, CAPT Ware,

Thank you for the note. I am copying RADMI Hinton to see if there is any information that may assist in this request.

V/R

Regards,

Susan M. Orsega
Rear Admiral, Commissioned Corps Headquarters Director
United States Public Health Service
Office of the Surgeon General /US Department of Health and Human Services
(b)(6)
Email: susan.orsega@hhs.gov

From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:22 PM
To: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo (FDA/CDER) <Khushboo.Sharma@fda.hhs.gov>
Subject: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Hello Ma'am,

I am reaching out on behalf of leadership in Office of New Drugs (OND) in CDER/FDA. We have received a CC officer request from high up in the US Government that we urgently need to discuss with you.

Would you please call Khushboo Sharma's office at 301-796-1270 as soon as you are able? Ms. Sharma is OND's Deputy Office Director for Operations.

Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service

Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience

Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-1160
Jacqueline.ware@fda.hhs.gov



THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please notify the sender immediately by e-mail or phone.

From: Nabakowski, Andrei [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]
Sent: 3/4/2020 9:14:53 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Thank you- understood, ma'am.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



**FDA U.S. FOOD & DRUG
ADMINISTRATION**

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:56 PM
To: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

(b)(5)

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:53 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Per OND: (b)(5) with Jim Sigg and Keagan Lenihan engaged and being worked. I have not spoke directly with either of them to confirm, but trust the CDER Ops DD and the loop would be closed.

I could reach out to Jim to verify (just let me know)

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison

Andrei.Nabakowski@fda.hhs.gov

Desk: 301-796-5205

Cell: (b)(6)

FCCA | FDA Commissioned Corps Affairs

OTS | Office of Talent Solutions



FDA U.S. FOOD & DRUG
ADMINISTRATION

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:51 PM
To: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND

Loop is closed – correct?

From: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Sent: Wednesday, March 4, 2020 8:49 PM
To: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Good evening, CAPT Ware,

Thank you for the note. I am copying RADM Hinton to see if there is any information that may assist in this request.

V/R

Regards,

Susan M. Orsega
Rear Admiral, Commissioned Corps Headquarters Director
United States Public Health Service
Office of the Surgeon General /US Department of Health and Human Services

(b)(6)
Email: susan.orsega@hhs.gov

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Sent: Wednesday, March 4, 2020 5:22 PM
To: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo (FDA/CDER) <Khushboo.Sharma@fda.hhs.gov>
Subject: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Hello Ma'am,

I am reaching out on behalf of leadership in Office of New Drugs (OND) in CDER/FDA. We have received a CC officer request from high up in the US Government that we urgently need to discuss with you.

Would you please call Khushboo Sharma's office at 301-796-1270 as soon as you are able? Ms. Sharma is OND's Deputy Office Director for Operations.

Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service

Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience

Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel 301-796-1160
Jacqueline.ware@fda.hhs.gov



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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/4/2020 9:23:47 PM
To: Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]
Subject: FYSA: draft inspection statement
Attachments: draft_inspection_3.4.20_915pm.docx

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 9:16 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: draft inspection statement

DRAFT DELIBERATIVE CONFIDENTIAL

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/5/2020 11:40:09 AM
To: Carter, Lionel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b4f0e18bfd24382b572355f0f15acdc-Lionel.Cart]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Mignone, Alfred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]; Russo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2b18c46a7bc4938a0609c76747e7456-Mark.Russo]; Koerner, Harold [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c565a7186ec422a9dc2baa096a5a9fe-Harold.Koer]
Subject: RE: COVID19 CONPLAN
Attachments: 20200304FDA_COVID19 CONPLAN_March_2020 V1.2.docx.docx

Lionel,

I agree with the approach in conducting reviews via SharePoint – this will help with version control. Please confirm whether this has been reviewed by the IMG and if each Center/ORAs has had an opportunity to review/comment. Either way, it can still be sent to the AEG for awareness. A goal would be to provide a briefing to the AEG/Commissioner in the EOC as early as possible next week after the Commissioner completes his budget hearing. Make sense?

Thanks,

Denise

From: Carter, Lionel <Lionel.Carter@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 6:45 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Koerner, Harold <Harold.Koerner@fda.hhs.gov>
Subject: COVID19 CONPLAN

Hello Admiral Hinton

Here is the Coronavirus Disease 2019 Outbreak (COVID19) Concept of Operations Plan. (b)(5)
(b)(5) We will probably need a technical editor to run through it quickly also, however the text has been updated based on the reviews that were able to be undertaken today by the IMG. I'd recommend that it be sent through the Offices/Centers (AEG) for a scrub and then we can finalize. It is also recommended we conduct that review via a SharePoint site. However if you prefer a different method we are certainly amenable to it. Apologies for the delay, however we wanted to make sure to address all comments.

V/r

Lionel Carter Acting Director
Office of Security and Emergency Management

10903 New Hampshire Avenue, WO32- RM1353

Silver Spring, MD 20993

PH:301-796-2796 | Mobile (b)(6)

Lionel.Carter@fda.hhs.gov

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/5/2020 3:20:33 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: RFI to ASPR

Thanks.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:09 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Agreed. As a first step, I've reached out to Anand. I've also been updating CDER. I next need to reach out to ASPR. But, agreed, I think an internal discussion is needed (including Center leadership and OCC).

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 05, 2020 2:28 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Probably needs a discussion.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 5, 2020 at 12:48:35 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 10:45 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: RFI to ASPR

Hi Keagan,

CDER (Johanna McLatchy) might already have contacted you about this. I just spoke with CDER about the attached RFI they've drafted, (b)(5)

(b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Sent: Thursday, March 05, 2020 9:51 AM
To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Subject: RFI to ASPR

Operations/Planning,

CDER asks that you send the attached memo to Dr. Kadlec at ASPR. CDER is requesting ASPR to create a list of approved drugs and therapeutic biologics that are being used to manage patients with COVID-19.

Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead

Sent: 3/5/2020 3:30:10 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: RFI to ASPR

Keagan – if his calendar allows, we can use the time immediately following

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:21 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

This is potentially something we could discuss on Tuesday morning with CDs and Dept Commish.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:09 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Agreed. As a first step, (b)(5) I've also (b)(5) I next need to (b)(5) But, agreed, I think (b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 05, 2020 2:28 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Probably needs a discussion.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

We could consider partnering, but maybe we need to discuss further because there are some internal concerns about fda developing such lists for interagency use, and also agreement that ASPR is probably better positioned to get a fuller, more accurate picture of what's "important" or "priority" from the manufacturer groups, clinician/health care community level, etc. Happy to talk more.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 5, 2020 at 12:48:35 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: RE: RFI to ASPR

I just sent you her email. I agree it should be ASPR, but we have a way bigger team and better access to these companies, right? Can we partner?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Sent: Thursday, March 5, 2020 10:45 AM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: FW: RFI to ASPR

Hi Keagan,

(b)(5)

(b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>

Sent: Thursday, March 05, 2020 9:51 AM

To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>

Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>

Subject: RFI to ASPR

Operations/Planning,

(b)(5)

Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
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CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: RFI to ASPR

Maybe next week.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:35 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Just a heads up I'll be on leave tomorrow, but happy to assist however helpful.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 05, 2020 3:34 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Maybe AEG tomorrow.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:32 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Keagan – if his calendar allows, we can meet following the check-in on Tuesday (0915) or the AEG w/principals or their one designee to keep small for discussion.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:21 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

This is potentially something we could discuss on Tuesday morning with CDs and Dept Commish.

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 05, 2020 2:28 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Probably needs a discussion.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 5, 2020 at 12:48:35 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 10:45 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: RFI to ASPR

Hi Keagan,

CDER (Johanna McLatchy) might already have contacted you about this. I just spoke with CDER about the attached RFI they've drafted. (b)(5)

(b)(5)

(b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>

Sent: Thursday, March 05, 2020 9:51 AM

To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>

Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>

Subject: RFI to ASPR

Operations/Planning,

CDER asks that you send the attached memo to Dr. Kadlec at ASPR. CDER is requesting ASPR to create a list of approved drugs and therapeutic biologics that are being used to manage patients with COVID-19.

Let me know if you have questions.

Rosemary Roberts

COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/5/2020 4:12:10 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: edits to sit rep
Attachments: 29_2019-nCoV Outbreak_FDA SITREP_4 March 2020 (003).docx

Hi! I went through yesterday's sit rep and re-ordered some things to make the most pertinent information up top. Just suggestions with the goal of making Michael's life a little easier.

Denise, give me a ring when you can so we can touch base

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 3/5/2020 4:35:23 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: RFI to ASPR

Good progress. Thanks Brooke.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Also, a quick update that I just spoke with Laura Wolf/ASPR to coordinate. She's in the process of planning a meeting with industry (e.g., PhRMA, BIO, AAM) for tomorrow to try to get a sense from them what products might be of priority for them. Also, over the summer, a list of 100 essential meds was developed by the private sector, so Laura is pulling that up. This is all to try to inform ASPR and FDA's development of a list, if that's still the plan after talking with leadership next week. Finally, Anand and I are schedule to talk at 5 today.

From: Courtney, Brooke
Sent: Thursday, March 05, 2020 3:50 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Thank you, I can be available either of those times (9:15, noon) and both days. I arrive around 7:30 and will make any time work.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, March 05, 2020 3:45 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

We can dedicate time to discuss during Monday's or Tuesday's noon AEG meeting or immediately following the commissioner check-in at 0915. Keagan -let us know if you have a preference. Brooke – please state your availability on either day. Thanks

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:36 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Maybe next week.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:35 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Just a heads up I'll be on leave tomorrow, but happy to assist however helpful.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 05, 2020 3:34 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Maybe AEG tomorrow.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:32 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Keagan – if his calendar allows, we can meet following the check-in on Tuesday (0915) or the AEG w/principals or their one designee to keep small for discussion.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:21 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

This is potentially something we could discuss on Tuesday morning with CDs and Dept Commish.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:09 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Agreed. As a first step, I've reached out to Anand. I've also been updating CDER. I next need to reach out to ASPR. But, agreed, I think an internal discussion is needed (including Center leadership and OCC).

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 05, 2020 2:28 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 5, 2020 at 12:48:35 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

I just sent you her email. (b)(5)

(b)(5)

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Sent: Thursday, March 5, 2020 10:45 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Hi Keagan,

CDER (Johanna McLatchy) might already have contacted you about this. I just spoke with CDER about the attached RFI they've drafted. (b)(5)

(b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Sent: Thursday, March 05, 2020 9:51 AM
To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning

<2019-nCoVFDAIMGPlanning@fda.hhs.gov>

Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>

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Operations/Planning,

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Let me know if you have questions.

Rosemary Roberts

COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/5/2020 4:55:48 PM
To: Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]
Subject: RE: For early review: Draft all hands email message from Dr. Hahn to staff on COVID 19 updates
Attachments: SMH all hands update on COVID 3.5.2020_OO.docx

From: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:43 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: For early review: Draft all hands email message from Dr. Hahn to staff on COVID 19 updates

Whatttttt

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:36 PM
To: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: For early review: Draft all hands email message from Dr. Hahn to staff on COVID 19 updates

Hi all,

Laura suggested I share this draft all-hands message with you for review ASAP today. Please let us know by 6:00 p.m. if possible if you have any edits or comments. Then I will share with the JIC. Specifically flagging your preference on where to refer people who have travel questions.
Thank you.

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov



From: Kahn, Jeremy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B98D36D2C1F4AE795140B68DE7B37F7-JEREMY.KAHN]
Sent: 3/5/2020 6:39:23 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: COVID-19 Health Fraud Warning Letters Press Release for 3/6
Attachments: COVID-19 WLs Press Release 3.5.20 OCC Cleared.docx
Importance: High

Good evening,

Passing along the OCC cleared version of the COVID-19 health fraud warning letters press release. I will be flagging for HHS momentarily.

Please let me know of any concerns or edits by 11:59pm.

Heidi/Laura- can this be flagged for the commissioner's review tonight?

We expect to go out with this sometime after 12pm tomorrow when the warning letters are ready for posting.

Please let me know if there are any questions.

Thank you,
--Jeremy

Jeremy Kahn
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-796-8671
jeremy.kahn@fda.hhs.gov



From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/5/2020 9:43:27 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Tse, Tania [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1256b0ce9d2c4351b5dff378211a4568-TSET]; Branch, Tiffany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b45f1b97b5d648f68cfff5ce4f75a154-Tiffany.Bra]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
Subject: RE: for urgent review tonight: statement on foreign inspections
Attachments: Inspection_statement_3.5.20_620pm.docx

Hi – some ideas. Use whatever works m

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Thursday, March 5, 2020 6:55 PM
To: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: for urgent review tonight: statement on foreign inspections

DRAFT, DELIBERATIVE, CLOSE HOLD

(b)(5)

Thank you,

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov



From: MacLennan, Lori [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7E3684D6A36E4002BC07015B7506B803-LORI.MACLEN]
Sent: 3/6/2020 11:12:44 AM
To: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; DeLancey, Siobhan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a414ba562dcd4c8284b1120074969b9a-SDELANCE]
Subject: RE: JIC AEG Review Requested by COB Today, Mar 4: APhA Coronavirus Emergency Responders-CDER

+ Jim Sigg (mistakenly included Linda Sigg in previous email)

Checking on status – is this cleared?

Thank you!

Lori

From: MacLennan, Lori
Sent: Wednesday, March 4, 2020 10:43 AM
To: Sigg, Linda A <Linda.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; DeLancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: JIC AEG Review Requested by COB Today, Mar 4: APhA Coronavirus Emergency Responders-CDER

Hi,

Requesting AEG clearance on a CDER-cleared journal article, which has been cleared by the JIC/IMG and OCC. The short article (750 words) is intended for publishing in the *Journal of the American Pharmacists Association* and is highly supported by CDER leadership to highlight the coronavirus response work of CDER's PHS officers. Can you please review the [APhA Coronavirus Emergency Responders](#) article on SharePoint by **COB today, Wed, Mar 4?**

Text included below for quick reference:

Novel Coronavirus Emergency Responders in FDA's Center for Drug Evaluation and Research
LCDR Andrea Gormley, PharmD, JD
CDR Kelly Ngan, PharmD, MPH, CPH

United States Public Health Service^[1] (USPHS) pharmacist officers in the Food and Drug Administration's (FDA) Center for Drug Evaluation and Research (CDER) are actively engaged in the 2019 novel coronavirus disease (COVID-19) response. These officers are trained to stand ready, engaging in a moment's notice for any new CDER emergency response. Pharmacist officers currently serve in "Incident Command System" positions such as Operations Section Chief and Planning Section Chief on CDER's official coronavirus (SARS-CoV-2) response task force. In these positions, they coordinate subject matter expert teams responding to urgent requests for information from federal government partners, including the Health and Human Services' Assistant Secretary for Preparedness and Response (ASPR) and Centers for Disease Control and Prevention (CDC). They assist in preparing CDER statements for the FDA Commissioner and legislative briefings to keep stakeholders informed of COVID-19 response activities.

There are currently no approved drug products for the prevention or treatment of COVID-19. Pharmacist officers are serving as Emergency Coordinators working directly with physicians of U.S. COVID-19 patients to enable access to investigational drugs for treatment under emergency Investigational New Drug (eIND) processes. These officers are on-call 24/7 to ensure health care providers across the U.S. can access FDA staff at any time to facilitate the use of investigational drugs when the patients they are treating have exhausted all approved drug product options.

With the globalization of the pharmaceutical supply chain, FDA is tasked with closely monitoring events that could threaten the U.S. supply of drug products. As part of the COVID-19 emergency response, CDER Drug Shortage Staff (DSS) pharmacist officers are actively monitoring drug supply chains related to components manufactured in China to anticipate and mitigate any drug product shortages resulting from manufacturing disruptions from the outbreak. Drug shortage situations can negatively impact patient care and challenge the tools available to health care providers, making this proactive supply chain monitoring a critical component of FDA's emergency response. DSS maintains frequent communication with manufacturers to help prevent drug shortages. As a resource for the public, FDA maintains a website for real-time information about drug shortages here: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Pharmacist officers are also engaged in teams that identify and evaluate promising investigational drug products for treatment or prevention of COVID-19, with a focus on fostering the development of candidate products to protect public health. To deliver the highest level of support for rapid product development, FDA supports the advancement of these promising candidates by providing scientific advice and regulatory guidance. Investigational products for SARS-CoV-2 could potentially be considered for use under FDA's Emergency Use Authorization (EUA) authority, which facilitates the availability and use of medical countermeasures needed during public health emergencies when certain criteria are met.

During emerging infectious disease outbreaks, FDA must be vigilant to protect the public from fraudulent products falsely claiming to prevent or treat COVID-19. Pharmacist officers contribute to FDA's task force dedicated to closely monitoring for fraudulent products and false product claims related to COVID-19. During public health emergencies, FDA is committed to identifying and taking regulatory action against products that mislead the public in the prevention or treatment of emerging infectious diseases.

Providing up-to-date information to the public is a critical component of emergency response. In CDER, pharmacist officers participate in FDA-wide communications teams charged with issuing key information for the public about the current outbreak. These officers developed a webpage that provides information about treatment options, fraudulent products, and FDA's emergency response resources. This team also has pharmacist officers in the Division of Drug Information (DDI) who answer direct questions from the public about coronavirus.

These examples provide a snapshot of the myriad responsibilities and duties of USPHS pharmacist officers at the FDA during a global public health emergency response. These pharmacist officers work tirelessly during emergencies such as COVID-19 to complete the mission: protecting public health by ensuring U.S. citizens have access to safe, effective, quality and available drug products.

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Acknowledgments: The authors gratefully acknowledge the following USPHS pharmacist officers for their FDA service and contributions to this article: CAPT Andrei Nabakowski, CAPT Val Jensen, CAPT Mary Kremzner, CAPT Paras Patel, CDR Ray Ford, CDR Larry Lim, CDR Rebecca McKinnon, LCDR Lena Choe, LCDR Carlos Gonzalez-Mercado, LCDR Gayle Tuckett, LT Renu Lal.

Initial CDER Document Clearance History:

- Initial Draft, CDER CTECS (AGormley, KNgan): 2/13/20
- Edits, cleared CDER DDI (MKremzner, LChoe): 2/14/20
- Edits, cleared CDER DSS (VJensen, PPatel): 2/14/20
- Edits, cleared CDER CTECS (AGormley, KNgan, RRoberts): 2/16/20
- Cleared, CDER OCD (DThrockmorton): 2/17/20
- Cleared, FDA Commissioned Corps Affairs-FCCA (ANabakowski): 2/19/20

Document History (JIC/IMG)

Insert lines as needed

Action:

Edited/ Reviewed/ Cleared	Center/Office	Name	Date	Time (use military format)
	CDER			
Cleared	CDRH CBER CVM	LMcNeill	03032020	1500

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	ORA			
	OPLIA/OGPS			
	OL			
	OCET			
	CoS			
Cleared	OCC	DKumar	3/4/2020	1011
	Copy Edit			
	Final/Published			

From: MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 10:15 AM
To: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: OCC Clearance (JIC FYI) Requested by 9am Wed, Mar 4: APhA Coronavirus Emergency Responders-CDER

Great, thank you!

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 10:11 AM
To: MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: OCC Clearance (JIC FYI) Requested by 9am Wed, Mar 4: APhA Coronavirus Emergency Responders-CDER

Hi Lori – clearing for OCC without change.

Thanks,
Dinesh

From: MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 2:38 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Subject: OCC Clearance (JIC FYI) Requested by 9am Wed, Mar 4: APhA Coronavirus Emergency Responders-CDER

Hi,

Requesting OCC clearance (and sending to JIC as an FYI) on a CDER-cleared journal article. The short article (750 words) is intended for publishing in the *Journal of the American Pharmacists Association* and is highly supported by CDER leadership to highlight the coronavirus response work of CDER's PHS officers. Can you please review the APhA Coronavirus Emergency Responders article on SharePoint **by 9am, Wed, Mar 4?**

Text included below for quick reference:

Novel Coronavirus Emergency Responders in FDA's Center for Drug Evaluation and Research
LCDR Andrea Gormley, PharmD, JD
CDR Kelly Ngan, PharmD, MPH, CPH

United States Public Health Service^[1] (USPHS) pharmacist officers in the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) are actively engaged in the 2019 novel coronavirus disease (COVID-19) response. These officers are trained to stand ready, engaging in a moment's notice for any new CDER emergency response. Pharmacist officers currently serve in "Incident Command System" positions such as Operations Section Chief and Planning Section Chief on CDER's official coronavirus (SARS-CoV-2) response task force. In these positions, they coordinate subject matter expert teams responding to urgent requests for information from federal government partners, including the Health and Human Services' Assistant Secretary for Preparedness and Response (ASPR) and Centers for Disease Control and Prevention (CDC). They assist in preparing CDER statements for FDA Commissioner and legislative briefings to keep stakeholders informed of COVID-19 response activities.

There are currently no approved drug products for the prevention or treatment of COVID-19. Pharmacist officers are serving as Emergency Coordinators working directly with physicians of U.S. COVID-19 patients to enable access to investigational drugs for treatment under emergency Investigational New Drug (eIND) processes. These officers are on-call 24/7 to ensure health care providers across the U.S. can access FDA staff at any time to facilitate the use of investigational drugs when the patients they are treating have exhausted all approved drug product options.

With the globalization of the pharmaceutical supply chain, FDA is tasked with closely monitoring events that could threaten the U.S. supply of drug products. As part of the COVID-19 emergency response, CDER Drug Shortage Staff (DSS) pharmacist officers are actively monitoring drug supply chains related to components manufactured in China, to anticipate and mitigate any drug product shortages resulting from manufacturing disruptions from the outbreak. Drug shortage situations can negatively impact patient care and challenge the tools available to health care providers, making this proactive supply chain monitoring a critical component of FDA's emergency response. DSS maintains frequent communication with manufacturers to help prevent drug shortages. As a resource for the public, FDA maintains a website for real-time information about drug shortages here: <https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.

Pharmacist officers are also engaged in teams that identify and evaluate promising investigational drug products for treatment or prevention of COVID-19, with a focus on fostering the development of candidate products to protect public health. To deliver the highest level of support for rapid product development, FDA supports the advancement of these promising candidates by providing scientific advice and regulatory guidance. Investigational products for SARS-CoV-2 could potentially be considered for use under FDA's Emergency Use Authorization (EUA) authority, which facilitates the availability and use of medical countermeasures needed during public health emergencies when certain criteria are met.

During emerging infectious disease outbreaks, FDA must be vigilant to protect the public from fraudulent products falsely claiming to prevent or treat COVID-19. Pharmacist officers contribute to FDA's task force dedicated to closely monitoring for fraudulent products and false product claims related to COVID-19. During public health emergencies, FDA is committed to identifying and taking regulatory action against products that mislead the public in the prevention or treatment of emerging infectious diseases.

Providing up-to-date information to the public is a critical component of emergency response. In CDER, pharmacist officers participate in FDA-wide communications teams charged with issuing key information for the public about the current outbreak. These officers developed a webpage that provides information about treatment options, fraudulent products, and FDA's emergency response resources. This team also has pharmacist officers in the Division of Drug Information (DDI) who answer direct questions from the public about coronavirus.

These examples provide a snapshot of the myriad responsibilities and duties of USPHS pharmacist officers at the FDA during a global public health emergency response. These pharmacist officers work tirelessly during emergencies such as

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COVID-19 to complete the mission: protecting public health by ensuring U.S. citizens have access to safe, effective, quality and available drug products.

Acknowledgments: The authors gratefully acknowledge the following USPHS pharmacist officers for their FDA service and contributions to this article: CAPT Andrei Nabakowski, CAPT Val Jensen, CAPT Mary Kremzner, CAPT Paras Patel, CDR Ray Ford, CDR Larry Lim, CDR Rebecca McKinnon, LCDR Lena Choe, LCDR Carlos Gonzalez-Mercado, LCDR Gayle Tuckett, LT Renu Lal.

Thank you!
Lori

Lori MacLennan

*Health Communications Specialist, External Communication Branch
CDRH Communications*

2019 Novel Coronavirus (COVID-19) Joint Information Center (JIC)

**Center for Devices and Radiological Health (CDRH)
Office of Communication and Education
Division of Communication
U.S. Food and Drug Administration**

Tel: 240-402-0962

lori.maclennan@fda.hhs.gov



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CC: Aviles, Natalie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: RE: COVID-19 PMO Call

Attachments: CLC guidance COVID-19 5-Mar-2020 v0.1 (003)-clean.docx

Please see attached COVID-19 guidance from VA on the protection of Veterans and staff for Community Living Centers.

-----Original Appointment-----

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>

Sent: Monday, March 2, 2020 10:36 AM

To: Mango, Paul (HHS/IOS); Pollard, Ashton (OS/IOS); Kadlec, Robert (OS/ASPR/IO); Shuy, Bryan (OS/ASPR/IO); McGowan, Robert (Kyle) (CDC/OD/OCS); Imbriale, Samuel (OS/ASPR/SIIM); Mccreary, Kenneth (OS/ASPR/SPPR); Perdue, Christopher (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Phillips, Sally (OS/ASPR/SPPR); Pratt, Michael (OS/ASPA); Lenihan, Keagan (FDA/OC); Mair, Michael (FDA/OC); Hinton, Denise (FDA/OC); Johnston, Darcie (HHS/IEA); Zebley, Kyle (HHS/OS/OGA); Chang, William (HHS/OGC); Trueman, Laura (HHS/IEA); Marston, Hilary (NIH/NIAID) [E]; Kerr, Lawrence (HHS/OS/OGA); Fernandez, Jose (OS/OGA); Elvander, Erika (OS/OGA); Valentine, Steven (HHS/OASH); Schwartz, Erica (HHS/OASH); Grigsby, Garrett (HHS/OS/OGA); Moudy, Robin (OS/ASPR/SPPR); Gregg, William (Joe) (CDC/DDID/NCIRD/OD); Patel, Anita (CDC/DDID/NCIRD/OD); Dreyzehner, John (CDC/DDPHSIS/CPR/OD); McNellis, Robert (AHRQ/CEPI); Levine, Cheryl (OS/ASPR/EMMO); Kouzoukas, Demetrios (CMS/OA); Kibunja, Julia (OS/OGA); Cochran, Norris (HHS/ASFR); Dasher, David (HHS/ASFR); Bettencourt, Alice (HHS/ASFR); Moughalian, Jen (HHS/ASFR); Hittle, Taylor (HHS/ASFR); Brookes, Brady (CMS/OA); Mignone, Alfred (FDA/OC); Parker, Jim (HHS/IOS); Agnew, Ann (HHS/IOS); Steele, Danielle (HHS/IOS); Brooks, John (CMS/OA); Stannard, Paula (HHS/IOS); Brady, Will (HHS/IOS); Uehlecke, Nick (HHS/IOS); Keckler, Charles (HHS/IOS); Smith, Brad (CMS/OA); Giroir, Brett (HHS/OASH); Horska, Katerina (HHS/IOS); Arbes, Sarah (HHS/ASL)

Cc: Aviles, Natalie (OS/ASPR/SIIM); Knutson, Donna (CDC/DDNID/NCEH/OD); Austin, Meredith (uscg.mil); OS Secretarys Operations Center; SOC Information Management Section Chief (OS/ASPR); Espinosa, Gregorio (OS/ASPR/SIIM); Birmingham, John (CDC/DDPHSIS/CPR/DEO); Maples, David L. (CDC/DDPHSIS/CPR/DEO); Harrison, Brian (HHS/IOS); Berger, Sherri (CDC/OCOO/OD); Hall, Bill (HHS/ASPA); Orsega, Susan (OS/OASH); Wong, Diana (OS/ASPR/SIIM); Asher, Jason (OS/ASPR/SIIM) (CTR); Clay, Matt (OS/ASPR/SIIM) (CTR); Seiler, Brittney (OS/ASPR/SIIM); Saxon, Bobby (CMS/CCIIO); Lekan, Scott (ACF); Payne, Skip (CMS/OA); Johnson, Robert (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Bright, Rick (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Wallace, Rodney (OS/ASPR/BARDA); Johnson, Lynn (ACF); Meyers, David (AHRQ/IOD); Wolf, Laura (OS/ASPR/SIIM); Farmer, William (OS/ASPR/SPPR); Blackford, Carol W. (CMS/CM); ASPR Data (HHS/ASPR); IMTNAT Information Management (OS/ASPR); Manning, Lelisa (OS/IOS); IMTNAT GROUP; Robinson, Wilma (HHS/IOS)

Subject: COVID-19 PMO Call

When: Friday, March 6, 2020 11:15 AM-12:15 PM (UTC-05:00) Eastern Time (US & Canada).

Where: 610F/Dial In Below

(b)(6) (b)(6)

<< File: HHS COVID-19 PMO Description_FINAL.pdf >> << File: COVID-19 HHS PMO Daily Sync Call Agenda.docx >>

From: Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]
Sent: 3/6/2020 1:38:32 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]; Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]
Subject: RE: Remarks for Hill Call at 1:50
Attachments: Reactive Responses for Denise - 3.6.20 .docx

And here are reactive responses

From: Tantillo, Andrew
Sent: Friday, March 6, 2020 1:34 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Remarks for Hill Call at 1:50

Andrew Tantillo

Deputy Director

Office of Legislation

U.S. Food and Drug Administration

O: 301-796-8919 | (b)(6)

andrew.tantillo@fda.hhs.gov



From: Farmer, William (OS/ASPR/SPPR) [William.Farmer@hhs.gov]
Sent: 3/6/2020 4:42:25 PM
To: Asher, Jason (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f026ebf942de4865944a935e4b2106dd-HHS-Jason.A]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Aviles, Natalie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=819bb9680d734e22944efc33d32f4f6f-HHS-Natalie]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Bermingham, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3f23d4114514e90908a9928c8ce526e-HHS-uvk7-cd]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Clay, Matt A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd2be2512f44fae9f59ac4aa02820c9-HHS-Matt.Cl]; CMS EPRO [EPRO@cms.hhs.gov]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Dreyzehner, John J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5f88b9bbd064adbb136f6769343ea6f-HHS-pwn3-cd]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Espinosa, Gregorio (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e58a1f33cc27486a9b7b2c8a789ed328-HHS-Gregori]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Foley, Diane (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9c12678c4be4b03a2ec404a221c4ed8-HHS-Diane.F]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Gregg, William J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ed1ebb891e44e8a073380a23746f82-HHS-hie6-cd]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Knutson, Donna B

(CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Kouzoukas, Demetrios (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87cab5d1c3fe48409195c03dd897988d-HHS-Demetri]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Maples, David L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47e6281952984095b3359c680e0387b9-HHS-idr0-cd]; Marks, Caryn L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e8a41c617994afa80efdda08b4c6053-HHS-Caryn.M]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCreary, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33bccf04199d4fd6948f0b933ce1623e-HHS-Kenneth]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63ed25c8067c4b838dbb689460ce0486-HHS-Susan.O]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; Parker, Jim (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0601902140f426e9c5a139f7134a3c5-HHS-Jim.Par]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Payne, Skip (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Pollard, Ashton (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0eba064633c94d69ac56385c0972e3da-HHS-Ashton.]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a57412715ab0f-HHS-Bobby.S]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Seiler, Brittney J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bec759d8a37149dd9a94b730ff725a9b-HHS-Brittne]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; SOC Information Management Section Chief (OS/ASPR) [SOC.IM@hhs.gov]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St];

Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Wallace, Rodney (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043f8bf8c4490b6b98a-HHS-Rodney.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebdddde-HHS-Kyle.Ze]

CC: Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]

Subject: Daily guidance update

Attachments: 003062020_GuidanceUpdateFinal.pdf

Good afternoon everyone,

Here is today's COVID-19 daily guidance update. As always, if you see something that needs to be changed or want to add something, please do not hesitate to contact myself or CAPT Perdue.

This guidance update is being sent out to the PMO list and others by request.

Hope you all enjoy the weekend

Very respectfully,
Will

William Farmer, MS

Presidential Management Fellow - Program Analyst
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements
Division of Requirements

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william.farmer@hhs.gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitzman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e81f80f531e04abda35a53af89b9270f-HHS-Matthew]; Greene, Jonathan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment

Location: Conference Number: 202 (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

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From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Thornton, Cody R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a7908b18a64fed92a3ddd40eb4c316-HHS-Diana.H]; Donato, Darrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59880927cd1c4c54898474f90a3cf036-HHS-Darrin.]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fcd76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Robinson, Shante R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b18b5bd335f44389c02-HHS-Shante.]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Newland, Matthew J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b4f1a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77fb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment

Location: Conference Number: (b)(6) Access Code (b)(6)

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)
Meeting Access Code: (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC

20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitzman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b4f1a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Canceled: COVID-19 Daily Disaster

Leadership Group Meeting
Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitzman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)
Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
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Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Wong, Diana (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Dodgen, Daniel (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Kellogg, Rachel (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Cederberg, Christina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Thornton, Cody R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a7908b18a64fed92a3ddd40eb4c316-HHS-Diana.H]; Donato, Darrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59880927cd1c4c54898474f90a3cf036-HHS-Darrin.]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fcd76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Robinson, Shante R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b18b5bd335f44389c02-HHS-Shante.]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Newland, Matthew J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b4f1a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77bfb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Number: (b)(6) Access Cod (b)(6)

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)
Meeting Access Code: (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
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From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitzman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Conference Number: (b)(6) Access Code (b)(6)

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitzman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
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From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4be86ef643374e818b9d590c649ff058-HHS-Daniel.]; Gettinger, Andrew (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=17c5a2d5b6284d2ca58f9de61500f3fe-HHS-Andrew.]; Abbey, Rachel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e7e829e079e04eb48bdb70b832423c8f-HHS-Rachel.]; Lennon, Todd (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96a7c26cba7943b2b2f9c9009c2f94d1-HHS-TLennon]; Dasher, David (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a56626cc3fe049fb88c26e56991755ae-HHS-David.D]; Kellogg, Rachel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Bettencourt, Alice (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cochran, Norris (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=996319874d544434b96eef30e8232610-HHS-norris.]; Cederberg, Christina (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4fc8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Bishop, Ralph (SAMHSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Thornton, Cody R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a7908b18a64fed92a3ddd40eb4c316-HHS-Diana.H]; Donato, Darrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59880927cd1c4c54898474f90a3cf036-HHS-Darrin.]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Robinson, Shante R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b18b5bd335f44389c02-HHS-Shante.]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Newland, Matthew J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b4f1a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77bfb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment
Location: Conference Number: (b)(6) Access Code: (b)(6)
Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily

every weekday from 3:00 PM to 4:00 PM

Required

Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR);

Attendees:

Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code: (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy

DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); DeBord, Kristin (OS/ASPR/SPPR); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA)

Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting
Location: Conference Number: (b)(6) Access Code (b)(6) Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM
Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy,

Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); DeBord, Kristin (OS/ASPR/SPPR); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA)

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Meeting Logistics & Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code: (b)(6)

These sessions will be held in conference room 624D.7, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. A conference line is provided for those of you unable to join the meeting in person.

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Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

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HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

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From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e01550a8d9664b51b3b4272d889ada77-HHS-Donald.]; Chaput, Daniel (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baaee1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Ethier, Kathleen A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7895b283237401cb312576b43fef452-HHS-kbe0-cd]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Brookes, Brady (CMS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f22e3142e1e84006b78a3552aa395ba0-HHS-DEspino]; Macrae, Jim (HRSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b768273650042db953632dc5635af8b-HHS-John.He]; Johnson, Robert (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Vineyard, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e9999fcd2dc4e97a7a7439aefe68737-HHS-Michael]; Mackay, Thomas F (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81c5959edf674a22af8b2374a2e659e1-HHS-alice.b]; Cochran, Norris (OS)

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Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily

every weekday from 3:00 PM to 4:00 PM

Required

Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR);

Attendees:

Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

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Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code: (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy

DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); DeBord, Kristin (OS/ASPR/SPPR); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA)

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment

Location: Conference Number: (b)(6) Access Code: (b)(6) | Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); DeBord, Kristin (OS/ASPR/SPPR); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO);

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Meeting Logistics & Conference Line

Conference Number: (202) (b)(6)
Meeting Access Code (b)(6)

These sessions will be held in conference room 624D.7, located in the Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201. A conference line is provided for those of you unable to join the meeting in person.

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3e9a9827a19d45ea9d08ddf7a8f586db-HHS-LCheeve]; Espinosa, Diana (HRSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e66849188c45449ca727fd52655aed-HHS-Francis]; Collins, Francis S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5257472fae794b85b15c27eb54598d70-HHS-collins]; Fauci, Anthony S (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitsman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=76c7c3188afa40368a755f8c8c16fc51-HHS-Eileen.]; Rucker, Donald (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a789d08141e044f4854cb6b3e1baaee1-HHS-Richard]; Phillips, Christine M (ACL) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7adf533419494821b7e0a05903204678-HHS-Christi]; Meyers, David (AHRQ)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Patel, Anita (CDC)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Payne, Skip (CMS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Hinton, Denise

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Cheever, Laura (HRSA)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48d004a5ea91438aa5ab85109c8a56ce-HHS-JMacrae]; Weahkee, Michael (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a89d8e26b8440b597e3f4ae278299f5-HHS-Michael]; McCollum, Jeffrey (IHS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6194598371fb4a088e78ef287d514b5e-HHS-Jeffrey]; Frazier, Francis (IHS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=759a71a9291b47a2bf83b77989d40cc3-HHS-afauci-]; Marston, Hilary D (NIH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCance-Katz, Elinore (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb4a446908694c3b930e5ed517aa6381-HHS-Elinore]; Delvecchio, Paolo (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a8156c0d75174cad8fce2f87bc88bea7-HHS-Paolo.D]; Lobos, Elisa (SAMHSA)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=869a5176139649c78543cff59b4eb1bf-HHS-Elisa.L]; Shuy, Bryan (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Yeskey, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=754752a933bb4079b8e5bec6f74841a9-HHS-Kevin.Y]; Bright, Rick (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Lambert, Linda (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffbd5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Phillips, Sally (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a431fbb31b9b4f8fbeb326c5e670d41c-HHS-Jonatha]; Cooper, Kevin (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2136f071b7074a529adc7c3e83cd5187-HHS-saa1-cd]; Lee, Scott (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS)

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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS)

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CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbc8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77bfb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM

End: 3/9/2020 4:00:00 PM

Show Time As: Busy

Recurrence: Daily

every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR);

Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy

DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
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From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=340427b44e5842fca8d779054a474b2d-HHS-Kevin.C]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Gin, Julia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Herrmann, John (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=e41c75e1f50247efb146f7b4611817a9-HHS-Thomas.]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Watson, Ryan (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code: (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=83b3a45ef78c4275bc278f0b65f72f3a-HHS-Mariam.]; Fucci, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c1b99c28ef04b1a8bf4f7492a500366-HHS-Michael]; Donnelly, Kelsey S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=73716e23a4fc4ab68ba02a72cce2abfd-HHS-Kelsey.]; Roman-Stolte, Claudia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=56ace3f975e9464f8b9df180e32ccf50-HHS-Claudia]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Hittle, Taylor (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12b1c0c5b2344e6080a6a0b06b214482-HHS-Taylor.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Bradsher, Kris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=945a2ca6355b43059a6dc1cf522f70e9-HHS-Kris.Br]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Destro, Brenda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b56a27640394f5089ed48c65c11eeb6-HHS-Brenda.]; Nevel, Amy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a2dcc7bb46584cfb8ae3a899b3289d33-HHS-Amy.Nev]; Tobias, Constance (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4bfa9cf0498949e6a606d9ae2ad763bf-HHS-Constan]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Severino, Roger (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79861e42509d47f982eacb431c01a055-HHS-Roger.S]; Bell, March (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97ed989ff2344059a12417ade318082c-HHS-March.B]; Frohboese, Robinsue (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a637e22cc00455cb274b102620c2030-HHS-Robinsu]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Taitzman, Julie (OIG) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19e0ea0f6b4a488c993a4a1ce3974792-HHS-Julie.T]; Griswold, Nancy J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8299c0880da64303b4ea8788eb1bb6c9-HHS-Nancy.G]; McDaniel, Eileen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

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(FYDIBOHF23SPDLT)/cn=Recipients/cn=937295b1bf5c4aeda0bd3fb0e6da0712-HHS-Julia.G]; Adams, Steven A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=3a88cca2be4740a8979f8df6f4151d48-HHS-Scott.L]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Wolf, Laura K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=729382a93c7242b3b1f32d1072540048-HHS-Laura.W]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=954c51879cef4cb28dd4947043cd56ea-HHS-Ryan.Wa]; Thornton, Cody R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=69ee27dc37974ab99e0465663d2122da-HHS-Cody.Th]; Cote, Mick Charles (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd639c2d85c4a00a8d822bbb3b8c6e8-HHS-Mick.Co]; Lawrence, Theresa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=b7b6a0d2fc644dd2b52138d5fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Robinson, Shante R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b18b5bd335f44389c02-HHS-Shante.]; Houchens, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7ffd780651964b4b999a0a9865886b23-HHS-Christo]; Newland, Matthew J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b4f1a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) [joselito.ignacio@fema.dhs.gov]; Chew, Heather (hq.dhs.gov) [Heather.n.chew@hq.dhs.gov]; john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil
CC: Cosgrove, Sandra (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f416746e5ab9ab745cd7b5edd-HHS-Sandra.]; Holland, Tara (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657dd8b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbaccdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=03b8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) [Jon.krohmer@dot.gov]; Haigwood, Patricia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f8b9f06515e886f4310-HHS-Patrici]; Donis, Ruben (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=dea126c25cab404db922973cd7ccb459-HHS-Ruben.D]; Oshansky, Christine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274e2cd8341f39d7ee4a9a1ecf405-HHS-Christi]; Cormier, Justin P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fe8a3d8dc9fb45bdbcb8d70a1eee33a31-HHS-Justin.]; Goyle, Suraj K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=51967bd65dd04a77bfb7cf44b7310dbc-HHS-Suraj.G]; Cabezas, Miriam (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e7414998aeb2c55ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19.Daily.Disaster Leadership Group Meeting

Location: Conference Number: (b)(6) Access Code (b)(6)

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily
every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinsue (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OMHA HQ); McDaniel, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCIRD/OD); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosa, Diana (HRSA); Macrae, Jim (HRSA); Weahkee, Michael (IHS/HQ); McCollum, Jeffrey T (IHS/HQ); Frazier, Francis (IHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillips, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/COOP); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbriale, Samuel (OS/ASPR/SIIM); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/DSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Gettinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dasher, David (HHS/ASFR); Rachel Kellogg (HHS/OS) (Rachel.Kellogg@hhs.gov); Bettencourt, Alice (HHS/ASFR); Norris Cochran (HHS/ASFR) (norris.cochran@hhs.gov); Cederberg, Christina (OS/ASPR/EEAA); Bishop, Ralph (SAMHSA); Watson, Ryan (SAMHSA); Thornton, Cody R. (OS/ASPR/SIIM); Cote, Mick (OS/ASPR/EMMO); Lawrence, Theresa (OS/ASPR/SPPR); Hadzibegovic, Diana (OS/ASPR/SPPR); Donato, Darrin (OS/ASPR/SPPR); Moughalian, Jen (HHS/ASFR); Colf, Leremy (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Robinson, Shante (OS/ASPR/SPPR) (CTR); Houchens, Christopher (OS/ASPR/BARDA); Newland, Matthew (OS/ASPR/BARDA); Mair, Michael (FDA/OC); awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV); Chew, Heather (hq.dhs.gov); john.p.polowczyk.mil@mail.mil; steven.p.whitney.mil@mail.mil

Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials

Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)

Meeting Access Code (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC
20515

o. (202) (b)(6)

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/6/2020 6:53:48 PM
To: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]
Subject: Close Hold: Your remarks at today's 2pm call
Attachments: Denise 3.6.20 BIPAR Hill Call Update-Clean - LP comments.docx; Reactive Responses for Denise - 3.6.20_.docx

Yes – please see attached document. Tim did a great job today – so thankful he was on the line and helped respond to questions.

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Friday, March 6, 2020 6:50 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Your remarks at today's 2pm call

Denise,

You have a really well done overview of the diagnostics space.

Can you please send over your script? We want to repurpose some of it for WH Press Conference tomorrow which we were just asked to provide info for

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/7/2020 9:39:07 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Can you pls fw me the working draft
Attachments: press briefing talkers_3.7.20 840am_clean.docx

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Saturday, March 7, 2020 9:38 AM
To: Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Can you pls fw me the working draft

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Saturday, March 07, 2020 9:37 AM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Can you pls fw me the working draft

So I can follow along... thx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/8/2020 10:07:51 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: COVID19 - with attachment this time
Attachments: JH CERSI COVID19 Resources 7MAR20.pdf
Importance: High

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>
Sent: Sunday, March 8, 2020 7:25 AM
To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Subject: FW: COVID19
Importance: High

FYI. As per discussion at Thursday's Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU's resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

*Audrey Thomas, M.S.
Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader
UCSF-Stanford CERSI Program Official (PO)
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 1, Rm 4220
Silver Spring, MD 20903
301-796-3520*

From: Caleb Alexander <galexan9@jhmi.edu>
Sent: Saturday, March 07, 2020 8:46 PM
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>
Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: COVID19
Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins' resources that may be relevant to FDA's COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc:d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH's Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA's response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/8/2020 10:07:59 AM
To: Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]
Subject: FYI: COVID19
Attachments: JH CERSI COVID19 Resources 7MAR20.pdf
Importance: High

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>
Sent: Sunday, March 8, 2020 7:25 AM
To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Subject: FW: COVID19
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*Audrey Thomas, M.S.
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10903 New Hampshire Avenue
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Sent: Saturday, March 07, 2020 8:46 PM
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>
Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: COVID19

Importance: High

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Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu

From: Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/8/2020 10:14:34 PM
To: Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: HHS Call
Attachments: 03082020 AllHandsUpdate for SMH review 5pm cleared.docx

Here you go! Thank you. Would you let know it has already been sent to ASPA.

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Sunday, March 8, 2020 10:04 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

Thanks Laura. Based on the call this evening, we should send the Commissioner's message through ASA as well. If you get me the final version, I can send to Blair or you can if you want.

Thanks,
Jim

From: "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 8, 2020 9:42 PM
To: "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>, "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>, "Hebert, Angelique A." <Angelique.Hebert@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

FYSA SH cleared his message. I have sent to ASPA and then VP clearance. I noted that Jim's mail was also submitted via Catherine Bird/ASA. My recommendation is that we send Dr. Hahn first, if possible, depending on how they come back. When you receive clearance, would you flag and I can check in on timing for SH. Will let you know when SH is cleared. If they aren't stacked, we can reassess.
LMK if you concur.

From: Caliguiri, Laura
Sent: Sunday, March 8, 2020 7:23 PM
To: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

Copy

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Sunday, March 8, 2020 7:09 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

Just heard from Catherine Bird. No need to resend my message. They are working to clear it. It might be as early as tonight.

From: "Caligui, Laura" <Laura.Caligui@fda.hhs.gov>

Sent: Sunday, March 8, 2020 6:19 PM

To: "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>, "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>, "Hebert, Angelique A." <Angelique.Hebert@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: HHS Call

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Sent: Sunday, March 8, 2020 6:12 PM

To: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: RE: HHS Call

Thanks for your update Jim. FWIW, I agree with the approach written in the last two sentences of the third bullet.

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>

Sent: Sunday, March 8, 2020 5:49 PM

To: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: HHS Call

On a 5:00 HHS call that ASA pulled together. Will Brady joined as well –

A few topics were discussed –

- Clearing our all-hands messages through HHS – Blair Duncan is our POC and we can copy ASPA at the same time
- FAQs – They would like to try to have a single point of entry for questions from staff. We discussed how we have already been receiving questions as have other Opdivs. Not sure what they are going to be able to pull together quickly as a point of entry but we were asked to send our questions and draft answers to Blair to serve as a resource for them,
- We need to tee up our decisions on travel for ASA and ASPA. I don't think this will be an issue. CDC explained what they are looking to do starting this week in cancelling all non-mission critical travel both domestic and foreign. I do

(b)(5)

From: OS CIP (HHS/OS) [CIP@hhs.gov]
Sent: 3/9/2020 12:02:34 PM
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Subject: Re: Supply Chain Taskforce Meeting

Attachments: Coronavirus Supply Chain Task Force_3.9.2020_FINAL.pdf

Please see the attached document for today's call.

From: OS CIP (HHS/OS)
Sent: Monday, March 9, 2020 11:07 AM
To: Alexandre, Gwendolyn (OS/ASPR/SIIM) (CTR) <Gwendolyn.Alexandre@hhs.gov>; Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; CIP Team Projects <Test964@HHS.GOV.onmicrosoft.com>; Cecere, Ashley (OS/ASPR/BARDA) <Ashley.Cecere@hhs.gov>; Disbrow, Gary (OS/ASPR/BARDA) <Gary.Disbrow@hhs.gov>; Figlio, Joseph (OS/ASPR/BARDA) <Joseph.Figlio@hhs.gov>; Rooks, Mercedes (OS/ASPR/BARDA) <Mercedes.Rooks@hhs.gov>; Angelastro, Michael (OS/ASPR/BARDA) <Michael.Angelastro@hhs.gov>; Francis, Troy (OS/ASPR/BARDA) <Troy.Francis@hhs.gov>; Marrero, Abraham (OS/ASPR/EMMO) <Abraham.Marrero@hhs.gov>; Finne, Kristen (OS/ASPR/EMMO) <Kristen.Finne@hhs.gov>; Link, Paul (OS/ASPR/EMMO) <Paul.Link@hhs.gov>; Czarzasty, James (OS/ASPR/EMMO) <James.Czarzasty@hhs.gov>; Brooks, Paul (OS/ASPR/IO) <Paul.Brooks@hhs.gov>; Allen, Ronald (OS/ASPR/OEA) <Ronald.Allen1@hhs.gov>; Stephan, Briana (OS/ASPR/SIIM) <Briana.Stephan@hhs.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; Aviles, Natalie (OS/ASPR/SIIM) <Natalie.Aviles@hhs.gov>; Fredenberg, John E. (CDC/SNS/DSNS) <dje5@cdc.gov>; Tewell, Adam (OS/ASPR/SPPR) <Adam.Tewell@hhs.gov>; Ayala, Ana (OS/ASPR/SPPR) <Ana.Ayala@hhs.gov>; Hrdina, Chad (OS/ASPR/SPPR) <Chad.Hrdina@hhs.gov>; Perdue, Christopher (OS/ASPR/SPPR) <Christopher.Perdue@hhs.gov>; Hadzibegovic, Diana (OS/ASPR/SPPR) <Diana.Hadzibegovic@hhs.gov>; Vineyard, Michael (OS/ASPR/IO) <Michael.Vineyard@HHS.GOV>; Fucci, Michael (OS/ASPR/SPPR) (CTR) <Michael.Fucci@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Balliram, Richard (OS/ASPR/SPPR) <Richard.Balliram@hhs.gov>; Moudy, Robin (OS/ASPR/SPPR) <Robin.Moudy@hhs.gov>; JACOB.J.CARTER@CBP.DHS.GOV <JACOB.J.CARTER@CBP.DHS.GOV>; lea-ann.b.bigelow@cbp.dhs.gov <lea-ann.b.bigelow@cbp.dhs.gov>; Prasher, Joanna (CDC/DDPHSIS/CPR/OD) <mex7@cdc.gov>; Ottem, Ronald (Ron) (CDC/SNS/DSNS) <rco9@cdc.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bop1@cdc.gov>; Dowell, Chad (CDC/NIOSH/OD) <crd7@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>; Brown, James (CDC/SNS/DSNS) <nhe0@cdc.gov>; Lewis, Stacey (CDC/SNS/DSNS) <ikd5@cdc.gov>; Dana.Ahrens@cisa.dhs.gov <Dana.Ahrens@cisa.dhs.gov>; Eric.Rollison@cisa.dhs.gov <Eric.Rollison@cisa.dhs.gov>; George.Renteria@cisa.dhs.gov <George.Renteria@cisa.dhs.gov>; georgette.holmes@cisa.dhs.gov <georgette.holmes@cisa.dhs.gov>; Jennifer.Pedersen@cisa.dhs.gov <Jennifer.Pedersen@cisa.dhs.gov>; Jenny.Margaros@cisa.dhs.gov <Jenny.Margaros@cisa.dhs.gov>; john.d.martin@hq.dhs.gov <john.d.martin@hq.dhs.gov>; robert.rutledge@cisa.dhs.gov <robert.rutledge@cisa.dhs.gov>; jenny.may@trade.gov <jenny.may@trade.gov>; Macintyre, Anthony (DHS.GOV) <anthony.macintyre@hq.dhs.gov>; gary.porter@hq.dhs.gov <gary.porter@hq.dhs.gov>; melissa.harvey@hq.dhs.gov <melissa.harvey@hq.dhs.gov>; reginald.mcdonald@hq.dhs.gov <reginald.mcdonald@hq.dhs.gov>; ryan.gibson@associates.hq.dhs.gov <ryan.gibson@associates.hq.dhs.gov>;

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Subject: Supply Chain Taskforce Meeting

Good afternoon TF members,

As a reminder, if you have not sent us your primary two department/agency contacts for supply chain task force work please do so **by 2pm today to cip@hhs.gov**. We will be working with these contacts to ensure regular touch bases and reporting on activities.

As mentioned, we will be using max.gov as our sharing platform for the task force. If you already have a max.gov account, you have been added to the [TF max page](#). If you do not have a max account, please follow the instructions below and email Luis.Deleon@hhs.gov once you create an account.

Today's call will be extended by 30 minutes to accommodate for a briefing by Premier Inc on supply chain challenges and global supply chain climate.

Below is the agenda

- 1-1:10 Task Force Overall Update, Processes & Info Sharing
- 1:15-1:45 Premiere Update
- 1:45- 2:10 RPDs
 - COA 1 Updates & Path Forward
 - COA 2 Updates & Path Forward
 - COA 3 Updates & Path Forward
 - COA 4 Updates & Path Forward
- 2:10-2:20 Line of Effort 2
 - Updates & Path Forward
- 2:20-2:30 Global Supply Chain
 - Updates & Path Forward

We look forward to speaking with you then. As a reminder, please login to the webex during the meeting.

**How to Register for a MAX.gov Account and
Accessing the HHS Interagency COVID-19 Supply Chain Task Force MAX webpage**

(b)(6)



MAX homepage and account registration button

From: Thomas, Audrey A [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E1250E3B21344CE89BD561FF8BAE53A-THOMASA]
Sent: 3/9/2020 3:50:47 PM
To: Wilson, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a78919ec52b7440e94f5928758847404-wilsonc]; Barratt, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7a14bd5dcfd4121849b18beffcebbdb-BARRATTR]; Mendrick, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2be78d4cfe4c8fa2685b38cbdd6e25-DMendrick]; Kwan, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c10cdb276014c4dae0b399f86ba64ff-Jonathan.Kw]; Braunstein, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4eb429abb54b56ae58a84d1c0077ba-BraunsteinE]; Nugent, Bridget [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=304aba05001b40518bc37dce94044ff8-Bridget.Nug]; Ruiz, Juan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b773dc886c0d4dfba2ee6919f5cc80e5-Juan.Ruiz]; Johanson, Elaine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Bright, Roselie A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4eef60c88912461ca085bcb876d3b45c-RXB]; Patel, Keyur [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70077d1043dc4a8bb0ef774865deb60f-Keyur.Patel]; Schneider, Julie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b938530b11846a29dca7d031cdf3d34-Julie.Schne]; Vasisht, Kaveeta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=829ef402d6284b4aab60db92ebada1dd-VASISHTK]; Lee, Christine (OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46b2c2861a86482589389aee84448588-LEECHRI]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAJOR]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Margerrison, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12386cee44f645b69f7215d42b265d70-Edward.Marg]; Saha, Anindita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f66659d5a8a4c6f8ffdbddccc7d312-AXS]
CC: Blumkemelor, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7676a976c93642f985adabb1f7ef2db8-Donna.Blumk]; Zinn, Rebekah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28f2489f571f4117971b764ce05a43a8-Rebekah.Zin]; Chada, Kinnera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6477a3fe02e40d7a6d7db5c40f92ba5-ChadaK]; Smith, Tara (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f75e433d7e564d7e848c5284e3921326-Tara.Smith]; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica [jessica.ritchie@yale.edu]; Ciaccio, Laura [laura.ciaccio@yale.edu]
Subject: RE: COVID19
Attachments: Yale University CERSI - COVID-19 Related Sources 030920 .docx

FYI. Please find attached a one-pager from Yale University CERSI on Yale's resources related to COVID-19. If you would like to connect with the Yale University, please contact Joe Ross at joseph.ross@yale.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A

Sent: Sunday, March 08, 2020 7:03 PM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Russ B Altman <Russ.Altman@stanford.edu>; 'Giacomini, Kathy' (Kathy.Giacomini@ucsf.edu) <Kathy.Giacomini@ucsf.edu>; 'Lin, Lawrence' (Lawrence.Lin@ucsf.edu) <Lawrence.Lin@ucsf.edu>; Friciello, Maria (Maria.Friciello@ucsf.edu) <Maria.Friciello@ucsf.edu>

Subject: RE: COVID19

FYI. Russ Altman reached out to me to say that Stanford is in the middle of a crisis. They have a faculty member at the Med School that has tested positive for coronavirus. The school is moving to online classes along with other restrictions. I told Russ not to worry about my request.

I think that this will become more and more prevalent

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(b)(6)

Audrey

From: Thomas, Audrey A

Sent: Sunday, March 08, 2020 11:59 AM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
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Subject: RE: COVID19

As requested, I have reached out to the CERSIs for information on their resources related to COVID-19. I just received a one-pager from the University of Maryland CERSI, Baltimore Campus. If you would like to connect with the University of Maryland, please contact James Polli at jpolli@rx.umaryland.edu (copied on this email).

Thanks.

Audrey Thomas

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>

Sent: Sunday, March 08, 2020 9:17 AM

To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>

Subject: RE: COVID19

Many thanks Audrey.

I shared with our CoV coordinator in CBER and we both think it would be great if you could reach out to each of the CERSIs with a similar request. Can't hurt to be more aware of all potentials out there.

Also, I'm assuming you are sharing the information with OCET as well.

Carolyn

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>

Sent: Sunday, March 8, 2020 7:25 AM

To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>

Subject: FW: COVID19

Importance: High

FYI. As per discussion at Thursday's Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU's resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.

Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader

UCSF-Stanford CERSI Program Official (PO)

Office of Regulatory Science and Innovation (ORSI)

Office of the Chief Scientist

Office of the Commissioner

Food and Drug Administration

10903 New Hampshire Avenue

Bldg. 1, Rm 4220

Silver Spring, MD 20903

301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>

Sent: Saturday, March 07, 2020 8:46 PM

To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>

Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: COVID19

Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins' resources that may be relevant to FDA's COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc'd Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH's Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA's response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/9/2020 4:21:08 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: TPs on Supply Chain
Attachments: 20200303_Master-TPs_for-editing.docx

Hi Denise,

I'm sorry, I'm still a little unclear about the TP ask for today. I've attached the most recent *draft* TPs from FDA (dated 3/3/20; not yet finalized), but I'm guessing that's probably not what's needed. I heard there might be a more updated document (e.g., reactive TPs or something like that) from the weekend? Again, my apologies.

Also, FDA participates in the following regular supply chain meetings/groups (plus a number of ad hoc meetings on various supply chain topics):

- FDA (internal) Supply Chain Work Group (weekly; all Centers and relevant Offices)
- HHS/OS Supply Chain Task Force (weekly)
- NSC Supply Chain Coordination Work Group (usually 2 times/week, plus subgroup meetings as needed)
- NAPAPI (as needed; meetings usually have some focus on supply chain)

Thanks,
Brooke

From: Courtney, Brooke
Sent: Monday, March 09, 2020 1:43 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

I can list each supply chain meeting being held that I'm aware of (it seems there are some I'm not aware of that OC is coordinating or participating in) and who's engaged (to the extent that I know, with the caveat that it might not be complete since, again, I'm not looped into all FDA activities on supply chain.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 09, 2020 1:12 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

Keagan was talking about the OS Supply Chain Taskforce Meeting that Stacy and Janet are attending. He will be going to the WHTF meeting this evening and could use updates for that, if any. It will be helpful to list out each supply chain meeting being held and who's engaged. You, Michael and I need to know what they are, who's covering, and what TPs are being used. Anything else?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 9, 2020 1:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

Thanks, I'm not sure I can get effective TPs together without knowing what the meeting is, and it seems there are other supply chain efforts going on within OC. Thanks.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 09, 2020 12:35 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

Will seek info from Keagan – it was mentioned walking from one meeting to another today.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 9, 2020 12:34 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: SupplyChain Taskforce Meeting

Hi Denise,

What is the "1:30 SC"? Also, I'm not aware of some of what's been going on with the NSC group and am concerned I don't have the most up to date information that he might need, but I'll see what I can pull together at 1:00 (I'm leading the internal supply chain WG call now, so I won't be able to send you any TPs until about 1:15 or so).

Thanks,
Brooke

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 09, 2020 12:28 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: Agenda in body of meeting: Supply Chain Taskforce Meeting

Please provide most current TPs for Dr. Hahn to reference and to speak to as needed in today's 1:30 SC and evening WHTF meeting.

Thanks,

Denise

From: OS CIP (HHS/OS) <CIP@hhs.gov>
Sent: Monday, March 9, 2020 11:08 AM
Subject: Supply Chain Taskforce Meeting

Good afternoon TF members,

As a reminder, if you have not sent us your primary two department/agency contacts for supply chain task force work please do so **by 2pm today to cip@hhs.gov**. We will be working with these contacts to ensure regular touch bases and reporting on activities.

As mentioned, we will be using max.gov as our sharing platform for the task force. If you already have a max.gov account, you have been added to the TF max page. If you do not have a max account, please follow the instructions below and email Luis.Deleon@hhs.gov once you create an account.

Today's call will be extended by 30 minutes to accommodate for a briefing by Premier Inc on supply chain challenges and global supply chain climate.



Below is the agenda

- 1-1:10 Task Force Overall Update, Processes & Info Sharing
- 1:15-1:45 Premiere Update
- 1:45- 2:10 RPDs
- COA 1 Updates & Path Forward
- COA 2 Updates & Path Forward
- COA 3 Updates & Path Forward

- COA 4 Updates & Path Forward
- 2:10-2:20 Line of Effort 2
- Updates & Path Forward
- 2:20-2:30 Global Supply Chain
- Updates & Path Forward

We look forward to speaking with you then. As a reminder, please login to the webex during the meeting.

**How to Register for a MAX.gov Account and
Accessing the HHS Interagency COVID-19 Supply Chain Task Force MAX webpage**

(b)(6)

From: Farmer, William (OS/ASPR/SPPR) [William.Farmer@hhs.gov]
Sent: 3/9/2020 4:37:06 PM
To: Aldana, Karen (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb4b2ef53443401a838b12397b6aec95-HHS-Karen.A]; Asher, Jason (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f026ebf942de4865944a935e4b2106dd-HHS-Jason.A]; Austin, Meredith (uscg.mil); (b)(6); Aviles, Natalie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=819bb9680d734e22944efc33d32f4f6f-HHS-Natalie]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Bermingham, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3f23d4114514e90908a9928c8ce526e-HHS-uvk7-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Ceballos, Kelly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68a916cfd4324e8bbe678c21d69a25e3-HHS-Kelly.C]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Clay, Matt A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd2be2512f44fae9f59ac4aa02820c9-HHS-Matt.Cl]; CMS EPRO [EPRO@cms.hhs.gov]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Dreyzehner, John J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5f88b9bbd064adbb136f6769343ea6f-HHS-pwn3-cd]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Espinosa, Gregorio (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e58a1f33cc27486a9b7b2c8a789ed328-HHS-Gregori]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Foley, Diane (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9c12678c4be4b03a2ec404a221c4ed8-HHS-Diane.F]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Gregg, William J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ed1ebb891e44e8a073380a23746f82-HHS-hie6-cd]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hittle, Matthew (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8372c80ded364f19bedb4a769a5fbe09-HHS-Matthew]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bffc7b280b7bc-HHS-Samuel.]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c3407905ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Kouzoukas, Demetrios (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group
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(FYDIBOHF23SPDLT)/cn=Recipients/cn=47e6281952984095b3359c680e0387b9-HHS-idr0-cd]; Marks, Caryn L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e8a41c617994afa80efdda08b4c6053-HHS-Caryn.M]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCreary, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=33bccf04199d4fd6948f0b933ce1623e-HHS-Kenneth]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Monroe, Johnathan (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=444fb883930644c5bbeabe0e21ba0054-HHS-Johnath]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=63ed25c8067c4b838dbb689460ce0486-HHS-Susan.O]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; Parker, Jim (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e0601902140f426e9c5a139f7134a3c5-HHS-Jim.Par]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Payne, Skip (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Pollard, Ashton (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=0eba064633c94d69ac56385c0972e3da-HHS-Ashton.]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Seiler, Brittney J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bec759d8a37149dd9a94b730ff725a9b-HHS-Brittne]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; SOC Information Management Section Chief (OS/ASPR) [SOC.IM@hhs.gov]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1faccfe0846fc-HHS-Judy.St]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Wallace, Rodney (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043f8bf8fc4490b6b98a-HHS-Rodney.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebdddde-HHS-Kyle.Ze]

CC: Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]

Subject: Daily guidance update

Attachments: 03092020_GuidanceUpdateFinal.pdf

Good afternoon everyone,

Here is today's COVID-19 daily guidance update. As always, if you see something that needs to be changed or want to add something, please do not hesitate to contact myself or CAPT Perdue.

This guidance update is being sent out to the HHS PMO list and others by request or need.

Very respectfully,
Will

William Farmer, MS

Presidential Management Fellow - Program Analyst
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements
Division of Requirements

HEALTH AND HUMAN SERVICES (HHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

Office: (202) (b)(6) | Mobile: (b)(6)
william.farmer@hhs.gov | www.phe.gov

From: Geraldine Hamilton [geraldine.hamilton@emulatebio.com]
Sent: 3/9/2020 5:35:46 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Fitzpatrick, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f01cfc45bf6443b89f16087a536b290e-SFitzpat]; Sebastian Hernandez [sebastian.hernandez@emulatebio.com]; Mendrick, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2be78d4cfe4c8fa2685b38cbdd6e25-DMendrick]
Subject: Re: Emulate | Organs-on-Chips | and COVID19

Hello Denise,

Hope you had a nice weekend. I know things must be super crazy right now. Just following up to see if you would have time connect on the COVID-19 and potential application of the Organs-on-Chips technology. We have some new developments that would be great to share with you and to explore how we can involve your team.

Best,
Geraldine.

On Feb 27, 2020, at 11:28 PM, Geraldine Hamilton <Geraldine.Hamilton@emulatebio.com> wrote:

Hello Denise,

Thanks so much for your prompt reply I know you must be super busy.

Tomorrow I am in the office in internal meetings most of the day so it is easy for me to step out and take your call. Please feel free to call my cell any time.

Looking forward to connecting.
Best,
Geraldine.

emulate

Geraldine A. Hamilton, PhD
President and Chief Scientific Officer

ME (b)(6)

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On Feb 27, 2020, at 10:45 AM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Good morning Geraldine.

It's great to hear from you. I am well and hope you are too. I am not available to meet today due to previously scheduled meetings; however, I am open to having discussions about the Emulate platform r/t COVID-19. I have your number below and will reach out to you at my earliest convenience to discuss. Let me know where you may have an opening today or tomorrow for a brief conversation and I'll try to make it work.

Thank you,

Denise

From: Geraldine Hamilton <geraldine.hamilton@emulatebio.com>
Sent: Wednesday, February 26, 2020 5:01 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Fitzpatrick, Suzanne <Suzanne.Fitzpatrick@fda.hhs.gov>; Sebastian Hernandez <sebastian.hernandez@emulatebio.com>
Subject: Emulate | Organs-on-Chips | and COVID19
Importance: High

Hello Denise,

Hope all is well with you. I wanted to reach out to you regarding the COVID-19 virus and the potential for the Emulate Organs-on-Chip technology to be applied to answer key questions related to the emerging novel coronavirus outbreak.

We have been communicating with our key contacts (b)(4) Based on their feedback and the questions being raised about the virus. We came up with 3 main ideas on how the Emulate platform could potentially be useful for the ongoing outbreak in two main ways:

(b)(4)

3. Efficacy and safety testing of potential antiviral therapeutic candidates

Here are links to some of our publications demonstrating the potential to use Organs-on-Chips for infectious disease:

<https://www.biorxiv.org/search/lung%2Bchip>

<https://www.biorxiv.org/content/10.1101/2020.02.03.931170v1>

<https://www.sciencedirect.com/science/article/abs/pii/S1931312819304160>

We are currently putting together a one-page document to capture this (b)(4)

(b)(4)

Do you think the FDA would like to be involved in this effort in some way? Would be great to discuss further and get your insights.

This may be very short notice but I plan to be in DC on Thursday - we could explore meeting in person if schedule aligns but totally understand that you must be super busy right now.

Look forward to hearing from you.

Best wishes,
Geraldine.

emulate

Geraldine A. Hamilton, PhD
President and Chief Scientific Officer

M: (b)(6)

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Sent: 3/9/2020 8:05:19 PM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: CDRH Readout Deliverables from 3/9 Monday

Thanks

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 9, 2020 6:34 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: CDRH Readout Deliverables from 3/9 Monday

Sorry I meant to include you on this!

From: McWilliams, Carly
Sent: Monday, March 9, 2020 6:30 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Cc: O'Callaghan, Kathryn <Kathryn.O'Callaghan@fda.hhs.gov>; Kamon-Brancazio, Jamie <Jamie.Kamon-Brancazio@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Diamond, Matthew <Matthew.Diamond@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov) <Keagan.Lenihan@fda.hhs.gov>
Subject: CDRH Readout Deliverables from 3/9 Monday

Hi CDRH, I know there have been a lot of emails today so I have done my best to compile the requests and divided by outstanding and completed (because it's important to note what you accomplished!). Please feel free to loop in those I missed. I am aware you are working on Cuomo info and I believe

(b)(5)

(b)(5)

To Do list of outstanding items Monday

Commissioner Call with Gov. Cuomo re concerns:

- "Your approval of the EUA amendment to allow us to add any hospital approved by us to do testing. We will: (b)(5) and
- We need more nasopharyngeal (NP) and oropharyngeal (OP) and viral transport media (VTM) as our stockpile is getting depleted by the Westchester sampling. Manufacturers are saying these are on backorder until may. (aware you are working on this)
- CDRH update on Wadsworth center's platform
- Status of NY EUA?

Expansion

(b)(5)

Ta-Da List (all of the things accomplished)

Change in swabs/Sample Collection

- FDA supports CDC's move to a single swab for testing, anticipating this change will allow more patients to be tested more quickly without posing any regulatory or supply chain difficulties.
- **ACTION/ Follow Up** We are finding out from large commercial labs if they have enough supplies for tests and also where they are with swabs to examine if there any critical vulnerabilities that will inhibit their fast ramp up. The team is contact the manufacturers of the swabs and find out about their ability to ramp up supply.

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(b)(5)

Q: Will the change to a single swab for testing require a new EUA or a supplement to the current EUA? Does it work like a regular application that got cleared/approved and then had a change? The commissioner asked for clarity on regulatory steps. ...Same question regarding the use of sputum test...

A: For the use of a single sample, as opposed to using multiple samples, no new EUA or EUA amendment would be necessary.

For use of a nasopharyngeal (NP) swab, an oropharyngeal (OP) swab, or sputum, no new EUA or EUA amendment would be necessary for any currently issued EUAs because the claims made by these organizations in their original EUA submission explicitly included analysis of "upper and lower respiratory specimens," which includes NP or OP swabs and sputum as well as lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate.

If new EUAs are issued to organizations making more limited claims, e.g. only claiming analysis of "upper respiratory specimens," and one wanted to use a lower respiratory specimen such as sputum, then an EUA amendment would normally be necessary, e.g. to add lower respiratory specimens to the test claims.

- Beginning assessment ASAP (today without delay) regarding status of the materials that are needed to perform sample collection for COVID diagnostics testing.
- The below excerpt was received from State of New York a short while ago:
- We need more nasopharyngeal (NP) and oropharyngeal (OP) and viral transport media (VTM) as our stockpile is getting depleted by the Westchester sampling.
- Matthew was tasked earlier today to assess the swab situation and now we have an escalating situation beyond swabs to include the transport medium in which the sample is carried.

• **Action Items**

1. Suzanne S requested 2 staff members from DARSS to help with this immediately to determine commercial labs supply of swabs, any vulnerabilities in the that will inhibit their first ramp up? Finding out ramp up supply

(b)(5)

} If you can

identify right away who those are....I will provide separate guidance but basically we will follow our procedures for assessing product availability.

2. Hahn Call with Gov Cuomo

WHO TESTS

- There has been some confusion about whether the World Health Organization developed and distributed a diagnostic test. WHO has not developed an in house test, however, they did support distribution of a test that was developed in Germany. They have facilitated the distribution of hundreds of thousands of

these tests worldwide to more than 100 countries, mostly low- and middle-income countries that did not have their own testing protocols.

- WHO selected this test in mid-January test because (1) it was manufactured according to international standards, (2) it was manufactured using the first validated published protocol for testing, and (3) because they knew about the manufacturing and distribution capabilities of the company producing the test.
- This test was distributed after self-validation of its accuracy. However, in the U.S. we require more validation before such wide spread use.
- CDC, which is a World Health Organization Essential Reference Laboratory also created a test like several other countries were doing. Until issues with the test were detected, which were rapidly resolved, there were no reasons to rely on another country's certified test.
- From an earlier exchange with (b)(4)

(b)(4)

(b)(5)

Contact for States

- (FL SG) Matthew Diamond

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/10/2020 11:07:33 AM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]
Subject: FW: Coronavirus Documents for March 9th

Would it be helpful for these to come to IMG/JIC?

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:03 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

+ Denise

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:02 AM
To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
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Cc: O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
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Hello Lindsay,

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Subject: RE: Coronavirus Documents for March 9th

Thanks for asking Lindsay. It can go the Centers; however, it would be helpful to send to the IMG AICs (Michael Mair and Alfred Mignone)/JIC (April Finnen) for awareness. Especially, if there is any action/response requested from any of the Centers/ORAs.

Thank you,

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/10/2020 11:21:44 AM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]; Mignone, Alfred [Alfred.Mignone@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]
Subject: FYSA: Coronavirus Documents for March 9th

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:21 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

Great, thanks!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:15 AM
To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

Thanks for asking Lindsay. It can go the Centers; however, it would be helpful to send to the IMG AICs (Michael Mair and Alfred Mignone)/JIC (April Finnen) for awareness. Especially, if there is any action/response requested from any of the Centers/ORAs.

Thank you,

Denise

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:03 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

+ Denise

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:02 AM
To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

Denise – can you connect with Lindsay on this? Do you think there is value in the IMG getting this info, or if it should still go right to the Centers?

I think it would be helpful if we were answering the kinds of questions the public want to know that is in our FDA lane, and this gives us some good perspectives of what people want to know.

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 10:18 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

Subject: FW: Coronavirus Documents for March 9th

Importance: High

Keagan – we get a ton of emails to the public box on COVID every day. I’ve started having OES send me the emails below but I’m now wondering if these should be sent to the working group? OES still farms assignments out per normal process but I’m wondering if Denise et al should have a chance to see what’s coming in earlier than later. OK for me to have OES send to WG?

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>

Sent: Monday, March 9, 2020 9:14 PM

To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>

Cc: O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>

Subject: Coronavirus Documents for March 9th

Importance: High

Hello Lindsay,

Sorry for the delay.

Wanda

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From: Tse, Tania [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1256B0CE9D2C4351B5DFF378211A4568-TSET]
Sent: 3/10/2020 11:41:06 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: FYSA: + slides - RE: Notes for 9:30 JIC meeting

Thanks!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:27 AM
To: Tse, Tania <Tania.Tse@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Subject: FYSA: + slides - RE: Notes for 9:30 JIC meeting

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 10:28 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: + slides - RE: Notes for 9:30 JIC meeting

New: Slides for today's 1:30 meeting RE streamlining the JIC process (send any thoughts before then, please)

Meeting notes are posted for reference. Thanks everyone for your continued help and support!

From: Finnen, April
Sent: Tuesday, March 10, 2020 7:43 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Mair, Michael (Michael.Mair@fda.hhs.gov) <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Notes for 9:30 JIC meeting

Good morning, JIC team.

After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

NOTE: Send all COVID-19-related OCC clearance requests to this mailbox, starting now:
OCCRequests-COVID19@fda.hhs.gov


30 minutes, WebEx/call only today. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

We'll cover:

- Cleared language to use publicly around canceled meetings; multiple centers/offices – Heidi to draft/clear w/OO 3/9 – update?
- Info for daily WH press briefing – what #s, etc. do we need today? Tweeting #s daily? (Stephanie)
- **New writing assignment (or copy/paste cleared info):** QA responses for Dr. Shah – add your center/office responses to this draft by **noon Thursday 3/12** (CDER, CBER, ORA, CVM, CFSAN, OCC, OCET)
- At this step we are drafting. Once input added, will route for JIC/IMG review.

- Will fold into cleared weekly TPs once finalized and cleared through OCC.
- Meeting report-out (all who covered meetings yesterday)
- Media monitoring (Anne)
- Status checks (see Reviews table below)
- Proactive: what's new / coming soon?

Reviews:

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Notes
<u>Senate HELP Letter on FDA Inspection Personnel</u>	March 5 COB <u>overdue</u>	Caitlin Pennington / Matthew Lockeed	Waiting on statement to go (likely Tuesday morning)	<u>Specifically need a response to Q4:</u> How is FDA communicating information and/or policies related to inspections in China to its workers and/or union representatives? ...
<u>Letter from Representatives Schakowsky, Doggett and DeLauro regarding COVID-19 testing capacity</u>	March 10, 10:00 a.m.	Taylor Price	JIC/IMG	In advance of the Commissioner's FY21 House Budget hearing on March 11, OCA is seeking to collect talking points for the Commissioner's use Optional (need CDRH input)
<u>MCMi stakeholder email</u>	March 10, 11:00 a.m.	April Finnen	JIC/IMG	
Coronavirus Health Fraud Products (Pre-recorded interview) Spanish (see email attachment →)	March 10, 11:00 a.m.	Gloria Sanchez-Contreras	JIC/IMG	 Coronavirus Health Fraud Products (Pre-
<u>Blood supply remarks Dr. Marks (comments on blood donation)</u>	March 10, 11:00 a.m.	Lorrie McNeill	JIC/IMG	previously-scheduled talk at the annual meeting of America's Blood Centers (ABC) on 3/10
<u>Consumer response letter</u>	March 10, 2:00 p.m.	April Finnen	JIC/IMG	Draft response for Dr. Hahn to consumer inquiry. Please use plain language.
<u>Letter from Sens. Warren & Casey on fraudulent products</u>	March 10, COB	Caitlin Pennington / Matthew Lockeed	JIC/IMG	
<u>Sen. Reed letter (OCA)</u>	March 10, COB	Taylor Price	JIC/IMG	On preparedness
<u>Sen. Murray letter on COVID-19 Testing</u>	March 12, COB	Caitlin Pennington / Matthew Lockeed	JIC/IMG	
<u>Op-ed on fraudulent products (link may be outdated version)</u>	TBD	Laura Caliguiri	ASPA	Cleared by Dr. Hahn March 4; stuck at HHS
FDA Voices on PHS all hands/response support	TBD	Brooke Leggin	Commissioner	Put in Commissioner's homework March 4 & 6 (next goes to ASPA?)

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Notes
<u>website FAQs (fda.gov)</u>	March 9, 9:00 a.m. <u>overdue</u>	Brooke Leggin	OCC (final step before we post)	Targeting to publish March 9 (does not AEG review – taken from previously cleared info)
<u>InsideFDA FAQs for employees</u>	March 5 <u>overdue</u>	Tina Harrison	OGC/GLD (clearing OO/HR Q&As, at OCC request)	JIC reviews completed March 6; with Tania Tse for GLD clearance
<u>APhA Coronavirus Emergency Responders</u>	March 4 <u>overdue</u>	Lori MacLennan / Lena Choe	Moved to HHS/ASPA at 2:00 p.m., 3/9; clearance requested by COB 3/11	Short article intended for publishing in the <i>Journal of the American Pharmacists Association</i> ; highly supported (+ cleared) by CDER leadership to highlight the response work of CDER's PHS officers
<u>COO all hands message on travel policy</u>	TBD	Sandy Walsh w/OO	Complete	JIC has not seen a draft; Update: message sent 3/9 – JIC not asked to review/clear (unclear what process this followed)
<u>FDA statement on inspections</u>	March 9	Heidi Rebello/ Stephanie Caccamo	ASPA/WH	JIC/IMG and OCC cleared 3/9 (target 3/10 to issue)
<u>Rep. Meng + 13 on COVID-19 testing</u>	March 13, COB	Caitlin Pennington/ Matthew Lockeed	JIC/IMG	
<u>Rep. Schakowsky, Doggett, & DeLauro letter on COVID-19 testing affordability</u>	March 16, COB	Caitlin Pennington/ Matthew Lockeed	JIC/IMG	
<u>Rep. Crist letter on Coronavirus diagnostic availability</u>	March 16, COB	Caitlin Pennington/ Matthew Lockeed	JIC/IMG	
Anything else currently in clearance?				
FUTURE COMMS				
Daily tweets	Daily before 3:00 p.m.	Abby Capobianco		Ongoing: time-sensitive Commissioner tweets need to be AEG-cleared before 3:00 p.m. daily
Weekend / evergreen tweets	Friday before 3:00 p.m. <u>Several overdue</u>	Abby Capobianco	AEG	Ongoing: need any Commissioner tweets for weekend AEG-cleared before 3:00 p.m. Fridays

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Notes
Weekly talking points	Weekly, Wednesdays at noon	Siobhan DeLancey		Ongoing (also updated w/new numbers, etc. when new statements are issued)
Statement on FDA response activities, to provide update on areas including diagnostics, inspections, and supply chain	TBD	Stephanie Caccamo	Drafting	

Reminders/notes/discussion:

- **Reminders:**
 - ACTION: Send Caitlin Pennington an email with your info for the JIC Contact list
 - SharePoint works best in Internet Explorer (if IE is not your default browser, copy/paste the SP links from emails)
 - No spaces in filename
 - Use the format YYYYMMDD_Filename
- **Things to bookmark:**
 - Main IMG SharePoint folder (review SITREPS daily, late afternoon)
 - Main JIC folder – includes clearance process checklist w/clearance legend
- **In progress:**
 - **Talking points vs. WH Task Force daily TPs vs. cleared media responses**
 - Updating TPs daily – this will be urgent task every day; will have updated talkers of the hot topic(s) of the day; OMA (Stephanie) will compile as a master list

Meeting report out / coverage (see Op Tempo for dial-in #s)

- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- White House press conference/TF
- 3/9 AEG discussion (Laura, Heidi, April) – FAQs Dr. Shah wants answers to questions below – JIC drafting responses:
 - Impact on critical medicines primarily made in the U.S.? (CDER / CBER / OCE)
 - Impact of wholesale disruptions to domestic inspections? (ORA)
 - Will I still be able to find pet food at my local store? (CVM)
 - Approach to unsafe food products or foodborne illness outbreaks? (CFSAN)
 - Are there additional opportunities for regulatory relief during the outbreak? (OCC)

Media monitoring report out (Anne) – notes on SharePoint

- ...

April Finnen

IMG JIC Lead

2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)

U.S. Food and Drug Administration

Desk 240-402-0470

EOC: 301-796-8281 (hours at EOC: Mon. & Thurs. 9:00 a.m. – 11:30 a.m., 1:00 – 3:00 p.m.)

Cell 240-507-7742

Email: (b)(6)

JIC (Joint Information Center) email: 2019-nCoVFDAIMGJIC@fda.hhs.gov



From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/10/2020 12:27:52 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: COV - Supply Chain Coordination Working Group - LOE 2 - Ventilators
Attachments: LOE2-Ventilators.3.10.20.docx

Denise and Michael,

As a heads up, the NSC Supply Chain Coordination WG has drafted a paper on ventilators. FDA and CDC already provided significant comments and edits, and the group met yesterday to discuss them. If you have any comments/edits on the attached, just let me know by 4:00 pm tomorrow (3/11)—CDRH already has this for review. We've been asked to return it to the NSC by tomorrow afternoon.

Thanks,
Brooke

From: Mroz, Sara K. EOP/NSC (b)(6)
Sent: Tuesday, March 10, 2020 12:20 PM
To: Chertow, Daniel S (NIH) (b)(6); Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Marston, Hilary D (NIH) <(b)(6)>; Waterman, Paige E. EOP/OSTP <(b)(6)>; Pillai, Satish K (CDC) <vig8@cdc.gov>; Jonas, Seth H. EOP/NSC (b)(6)
Cc: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Esbitt, Deborah L (CDC) <dhe1@cdc.gov>; Mitchell, Catherine L (CDC) <vqk3@cdc.gov>; Ottem, Ronald S (CDC) <rco9@cdc.gov>
Subject: COV - Supply Chain Coordination Working Group - LOE 2 - Ventilators

All,
Thank you for a productive call yesterday afternoon.
Attached, please find the next round of a **draft** of the COA paper for ventilators. I tried to incorporate the edits that you sent last week as well as things I captured in my notes yesterday.
Please fact check, add thoughts, edits, etc.
Appreciate your edits by **5pm EDT on March 11**.
Thank you in advance.
Please reach out with any questions or concerns.
-Sara

Sara K. Mroz
National Security Council, Resilience Directorate
(b)(6)

(b)(5)

From: Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]
Sent: 3/10/2020 3:02:26 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]
Subject: FW: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]
Attachments: 030620208001 COVID-19 Prep Act - Report To Congress 03-06-2020.docx; 030620208001 COVID-19 PREP Act - ASPR to Sec DM 03-06-2020.docx; 030620208001 COVID-19 PREP Act - ASPR to Sec Final Sign 03-10-2020.pdf; PREP Act Declaration-RPC PS SS MC edits-3-10-20 CLEAN VERSION 12 15 PM.docx; Congressional Notifications (House).docx; Congressional Notifications (Senate).docx
Importance: High

Keagan, Erika, Stacy, Denise, Michael –

We just received a copy of the attached documents from the department. **Deadline is 3:30 today.** We can quickly review in OP; does anyone else in FDA need to see it?

From: Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 2:59 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Helmanis, Lisa M <Lisa.Helmanis@fda.hhs.gov>; Gillum, Jessica Z (FDA) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Rooths, Tarita <Tarita.Rooths@fda.hhs.gov>
Subject: FW: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]

Hi, flagging this package; it did not come to us in SPS and I spoke with Martina and it does not appear it went to her shop in SPS either. Martina: (b)(5) There is a FR notice in the package. Please let us know if we PECS should review this (or you or other parties). Note that the requested due time is 3:30 today.
Ken

From: Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>
Sent: Tuesday, March 10, 2020 2:11 PM
To: Bradsher, Kris (OS) <Kris.Bradsher@hhs.gov>; Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Tatem, Anne (OS) <Anne.Tatem@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; ASPE Exec Sec (OS/ASPE) <ASPEExecSec@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Clark, Cynthia (CDC) <cfc8@cdc.gov>; Hoffmann, Lauren (CDC) <cpf5@cdc.gov>; Campbell, Taylor (OS) <Taylor.Campbell@hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; Gillum, Jessica Z (FDA) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Varnado, Martina

<Martina.Varnado@fda.hhs.gov>; Allen-Gifford, Patrice L (NIH) <patrice.allen-gifford@nih.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Bird, Catherine (OS) <Catherine.Bird@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Clark, Cynthia (CDC) <cfc8@cdc.gov>; Hecht, Jonah (OS) <Jonah.Hecht@hhs.gov>; Hittle, Taylor (OS) <Taylor.Hittle@hhs.gov>; Hoffmann, Lauren (CDC) <cpf5@cdc.gov>; Moughalian, Jen C (OS) <Jen.Moughalian@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Schaeffer, Alison M (OS) <Alison.Schaeffer@hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Strom, John (OS) <John.Strom@hhs.gov>; Thomas, Gloria D (OS) <Gloria.Thomas@hhs.gov>; White, Caroline (OS) <Caroline.White@hhs.gov>
Cc: Agnew, Ann (OS) <Ann.Agnew@hhs.gov>; Robinson, Wilma (OS) <Wilma.Robinson@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>; Hawkins, Jamar (OS) <jamar.hawkins@hhs.gov>; Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>; Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; Bird, Catherine (OS) <Catherine.Bird@hhs.gov>

Subject: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]

Good afternoon – please find attached the below-referenced PREP Act Declaration package. Attached is the Declaration (FRN), memo to Secretary in Word and PDF, as well as a Report to Congress and transmittal letters.

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Thank you,

Katerina

Katerina Horska

Policy Coordinator

Immediate Office of the Secretary, Executive Secretariat

U.S. Department of Health & Human Services

Room 629H, Humphrey Building

Office: 202-690-6819

Cell: (b)(6)

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Sent: Tuesday, March 10, 2020 12:06 PM

To: Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; ASPE Exec Sec (OS/ASPE) <ASPEExecSec@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; Gillum, Jessica Z (FDA) (FDA/OC) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Varnado, Martina (FDA/OC) <Martina.Varnado@fda.hhs.gov>; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-gifford@nih.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Schaeffer, Alison (HHS/OS/OGA) <Alison.Schaeffer@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stimson, Brian (HHS/OGC)

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Subject: Forthcoming PREP Act Declaration Today [COVID-19]

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For your awareness

(b)(5)

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documents when they are ready for your clearance.

Quick background summary from ASPR: Liability protections under the Public Health Readiness and Emergency Preparedness (PREP) Act are needed to encourage development and use of diagnostics, use of personal respiratory devices, and development of antivirals and vaccines against the spread of COVID-19, consistent with the terms of the Secretary's Public Health Emergency Declaration.

Thank you,

Katerina

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Policy Coordinator

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U.S. Department of Health & Human Services

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Phone: 202-690-6819

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Sent: 3/10/2020 3:15:53 PM
To: Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]
Subject: FW: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]
Attachments: 030620208001 COVID-19 Prep Act - Report To Congress 03-06-2020.docx; 030620208001 COVID-19 PREP Act - ASPR to Sec DM 03-06-2020.docx; 030620208001 COVID-19 PREP Act - ASPR to Sec Final Sign 03-10-2020.pdf; PREP Act Declaration-RPC PS SS MC edits-3-10-20 CLEAN VERSION 12 15 PM.docx; Congressional Notifications (House).docx; Congressional Notifications (Senate).docx
Importance: High

Adding Liz

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Sent: Tuesday, March 10, 2020 3:02 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>
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Importance: High

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Sent: Tuesday, March 10, 2020 2:59 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Helmanis, Lisa M <Lisa.Helmanis@fda.hhs.gov>; Gillum, Jessica Z (FDA) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Rooths, Tarita <Tarita.Rooths@fda.hhs.gov>
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Katerina Horska
Policy Coordinator
Immediate Office of the Secretary, Executive Secretariat
U.S. Department of Health & Human Services
Room 629H, Humphrey Building
Phone: 202-690-6819

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Sent: 3/10/2020 3:37:04 PM
To: Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Cohen, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44f565b739ea4879bdc516caf2e136bc-Kenneth.Coh]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]
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Importance: High

Hi Lauren,

OCS/OCET reviewed and clears with no comments or proposed revisions. Liz specifically reviewed the relevant section re: "covered countermeasures" and that reads as we had previously recommended.

Thanks,

Denise

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Sent: Tuesday, March 10, 2020 3:02 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Subject: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]

Good afternoon – please find attached the below-referenced PREP Act Declaration package. Attached is the Declaration (FRN), memo to Secretary in Word and PDF, as well as a Report to Congress and transmittal letters.

OGC and Paula Stannard have already reviewed the FRN. Please let me know if you have any concerns or edits to any of the documents by **NLT 3:30 PM today**. We are aiming to sign the package today.

Thank you,

Katerina

Katerina Horska

Policy Coordinator

Immediate Office of the Secretary, Executive Secretariat

U.S. Department of Health & Human Services

Room 629H, Humphrey Building

From: Horska, Katerina (HHS/IOS)

Sent: Tuesday, March 10, 2020 12:06 PM

To: Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; ASPE Exec Sec (OS/ASPE) <ASPEExecSec@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; Gillum, Jessica Z (FDA) (FDA/OC) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Varnado, Martina (FDA/OC) <Martina.Varnado@fda.hhs.gov>; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-gifford@nih.gov>; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Schaeffer, Alison (HHS/OS/OGA) <Alison.Schaeffer@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>

Cc: Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>

Subject: Forthcoming PREP Act Declaration Today [COVID-19]

Good morning,

For your awareness

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(b)(5)

I will share the

documents when they are ready for your clearance.

Quick background summary from ASPR: Liability protections under the Public Health Readiness and Emergency Preparedness (PREP) Act are needed to encourage development and use of diagnostics, use of personal respiratory devices, and development of antivirals and vaccines against the spread of COVID-19, consistent with the terms of the Secretary's Public Health Emergency Declaration.

Thank you,

Katerina

Katerina Horska

Policy Coordinator

Immediate Office of the Secretary, Executive Secretariat

U.S. Department of Health & Human Services

Room 629H, Humphrey Building

Phone: 202-690-6819

From: Mignone, Alfred [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EAED5E63933B450185F262AC50F80931-ALFRED.MIGN]
Sent: 3/10/2020 4:44:03 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: FDA COVID19 CONOP Plan
Attachments: FDA_COVID19 CONPLAN_March_2020 V2.0.docx

Good afternoon,

The attached has been submitted to OO for review. It still needs a technical editor polish it up, as we ran out of time to have that undertaken here. We were able to capture the additions and addressed most if not all of the questions/comments (last set received at 14:13 today). Please let me know if you have any questions and/or concerns.

v/r

Tom

CAPT Thomas Mignone

Deputy Agency Incident Coordinator

2019 Novel Coronavirus (nCoV) IMG

U.S. Food and Drug Administration

Desk 301-796-7635

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Email: alfred.mignone@fda.hhs.gov

From: Carter, Lionel <Lionel.Carter@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:34 PM
To: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Cc: Yancey, Carolyn A (OCIO) <Carolyn.Yancey@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Subject: FDA COVID19 CONOP Plan

Jim

Here is the CONOP Plan for COVID19. I believe we have captured all the comments/edits that were provided to us by 10 pm on Monday, March 9, 2020. However, I believe Monica Ellerbe is currently working on updates for OFBA. We can discuss how to incorporate any comments they may have after your review. I just did not want to hold this up any longer.

V/r

Lionel Carter Acting Director
Office of Security and Emergency Management
10903 New Hampshire Avenue, WO32- RM1353
Silver Spring, MD 20993
PH:301-796-2796 | Mobile: (b)(6)
Lionel.Carter@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/10/2020 5:32:25 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mignone, Alfred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eaed5e63933b450185f262ac50f80931-Alfred.Mign]
Subject: For REVIEW: COVID-19 PMO Materials for March 11, 2020
Attachments: COVID-19 HHS PMO Daily Sync Call Agenda_FINAL.docx; COVID-19 HHS PMO Summary 2020-03-10.docx; COVID-19 PMO Tracker 3-10.docx

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>

Sent: Tuesday, March 10, 2020 5:25 PM

To: Pollard, Ashton (OS) <Ashton.Pollard@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Imbriale, Samuel (OS) <Samuel.Imbriale@hhs.gov>; McCreary, Kenneth (OS) <Kenneth.McCreary@hhs.gov>; Perdue, Christopher (OS) <Christopher.Perdue@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Pratt, Michael (OS) <Michael.Pratt@hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Trueman, Laura (OS) <Laura.Trueman@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Fernandez, Jose A (OS) <Jose.Fernandez@hhs.gov>; Elvander, Erika (OS) <Erika.Elvander@hhs.gov>; Valentine, Steven (OS) <Steven.Valentine@hhs.gov>; Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Moudy, Robin (OS) <Robin.Moudy@hhs.gov>; Gregg, William J (CDC) <hie6@cdc.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Dreyzehner, John J (CDC) <pwn3@cdc.gov>; McNellis, Robert (AHRQ) <Robert.McNellis@ahrq.hhs.gov>; Levine, Cheryl (OS) <Cheryl.Levine@hhs.gov>; Kouzoukas, Demetrios (CMS) <Demetrios.Kouzoukas@cms.hhs.gov>; Kibunja, Julia (OS) <Julia.Kibunja@hhs.gov>; Cochran, Norris (OS) <norris.cochran@hhs.gov>; Dasher, David (OS) <David.Dasher@hhs.gov>; Bettencourt, Alice (OS) <alice.bettencourt@hhs.gov>; Moughalian, Jen C (OS) <Jen.Moughalian@hhs.gov>; Hittle, Taylor (OS) <Taylor.Hittle@hhs.gov>; Brookes, Brady (CMS) <Brady.Brookes@cms.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Parker, Jim (OS) <Jim.Parker@hhs.gov>; Agnew, Ann (OS) <Ann.Agnew@hhs.gov>; Steele, Danielle (OS) <Danielle.Steele@hhs.gov>; Brooks, John (CMS) <John.Brooks@cms.hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Brady, William (OS) <William.Brady@hhs.gov>; Uehlecke, Nicholas (OS) <Nicholas.Uehlecke@hhs.gov>; Keckler, Charles (OS) <Charles.Keckler@hhs.gov>; Smith, Brad (CMS) <Brad.Smith@cms.hhs.gov>; Giroir, Brett (OS) <Brett.Giroir@hhs.gov>; Horska, Katerina (OS) <Katerina.Horska@hhs.gov>; Arbes, Sarah C (OS) <Sarah.Arbes@hhs.gov>; Baker, Michael G (OS) <Michael.Baker@hhs.gov>; Lincoln, Carol (OS) <Carol.Lincoln@hhs.gov>; Newland, Matthew J (OS) <Matthew.Newland@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Destro, Brenda (OS) <Brenda.Destro@hhs.gov>; Nevel, Amy (OS) <Amy.Nevel@HHS.GOV>; Twomey, John K (OS) <John.Twomey@HHS.GOV>; Bradway, Courtney B (OS) <Courtney.Bradway@hhs.gov>; Weahkee, Michael (IHS) <Michael.Weahkee@ihs.gov>; Paden, Maris (OS) <Maris.Paden@hhs.gov>; Shuy, Caitrin (OS) <Caitrin.Shuy@hhs.gov>; Aasen, Adam (OS) <Adam.Aasen@hhs.gov>; Robertson, Lance (ACL) <Lance.Robertson@acl.hhs.gov>; McGuffee, Tyler Ann (OS) <Tylerann.McGuffee@hhs.gov>
Cc: Aviles, Natalie (OS) <Natalie.Aviles@hhs.gov>; Knutson, Donna B (CDC) <dbk2@cdc.gov>; Austin, Meredith (uscg.mil) <Meredith.L.Austin@uscg.mil>; OS Secretarys Operations Center <hhs.soc@hhs.gov>; SOC Information Management Section Chief (OS/ASPR) <SOC.IM@hhs.gov>; Espinosa, Gregorio (OS) <Gregorio.Espinosa@hhs.gov>; Birmingham, John (CDC) <uvk7@cdc.gov>; Maples, David L (CDC) <idr0@cdc.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Berger,

Sherri (CDC) <sob8@cdc.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Orsega, Susan (OS) <Susan.Orsega@hhs.gov>; Wong, Diana (OS) <Diana.Wong@hhs.gov>; Asher, Jason (OS) <Jason.Asher@hhs.gov>; Clay, Matt A (OS) <Matt.Clay@hhs.gov>; Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>; Saxon, Bobby (CMS) <Bobby.Saxon@cms.hhs.gov>; Lekan, Scott M (ACF) <Scott.Lekan@acf.hhs.gov>; Payne, Skip (CMS) <Skip.Payne@cms.hhs.gov>; Johnson, Robert (OS) <Robert.Johnson@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Johnson, Lynn (ACF) <Lynn.Johnson@acf.hhs.gov>; Meyers, David (AHRQ) <David.Meyers@ahrq.hhs.gov>; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Farmer, William (OS) <William.Farmer@hhs.gov>; Blackford, Carol W (CMS) <Carol.Blackford@cms.hhs.gov>; ASPR Data (HHS/ASPR) <ASPRDATA@hhs.gov>; IMTNAT Information Management (OS/ASPR) <IMTNAT.Info@hhs.gov>; Manning, Lelisa (OS) <Lelisa.Manning@hhs.gov>; IMTNAT GROUP <IMTNAT.GROUP@hhs.gov>; Robinson, Wilma (OS) <Wilma.Robinson@hhs.gov>; Coleman, Mary (OS) <Mary.Coleman@hhs.gov>; Compton, Kimberly <Kimberly.Compton@fda.hhs.gov>; Taylor, Reginald E (NIH) <reginald.taylor@nih.gov>; FEMA-NRCC-sasc (DHS.GOV) <fema-nrcc-sasc@fema.dhs.gov>; Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>; Nestor, Johanna (OS) <Johanna.Nestor@hhs.gov>; Herrmann, John (OS) <John.Herrmann@hhs.gov>; Finne, Kristen (OS) <Kristen.Finne@hhs.gov>; Cosgrove, Sandra (OS) <Sandra.Cosgrove@hhs.gov>; Lapkoff, James H (OS) <James.Lapkoff@hhs.gov>; Mason, Byron R (ACF) <Byron.Mason@acf.hhs.gov>; Grant, Natalie (ACF) <Natalie.Grant@acf.hhs.gov>; Palosky, Stacey (OS) <Stacey.Palosky@hhs.gov>; Haddad, Carla (OS) <Carla.Haddad@hhs.gov>; Dafflitto, Scott (OS) <Scott.Dafflitto@hhs.gov>; Moran, Thomas (ACL) <Thomas.Moran@acl.hhs.gov>; Votava, Kathleen (ACL) <Kathleen.Votava@acl.hhs.gov>; Houchens, Christopher (OS) <Christopher.Houchens@hhs.gov>; Nicholls, Richard (ACL) <Richard.Nicholls@acl.hhs.gov>; Phillips, Christine M (ACL) <Christine.Phillips@acl.hhs.gov>

Subject: COVID-19 PMO Materials for March 11, 2020

PMO Team: Here are the materials for tomorrow's meeting:



COVID-19 HHS
PMO Daily Sync ..



COVID-19 HHS
PMO Summary 2...



COVID-19 PMO
Tracker 3-10.docx

Also, I am including the final infection control guidance hotlink of the document ASPA cleared near the end of our meeting today

https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html

From: Farmer, William (OS/ASPR/SPPR) [William.Farmer@hhs.gov]
Sent: 3/10/2020 7:23:30 PM
To: Aldana, Karen (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb4b2ef53443401a838b12397b6aec95-HHS-Karen.A]; Asher, Jason (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f026ebf942de4865944a935e4b2106dd-HHS-Jason.A]; Austin, Meredith (uscg.mil) [Meredith.L.Austin@uscg.mil]; Aviles, Natalie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=819bb9680d734e22944efc33d32f4f6f-HHS-Natalie]; Bedan, Morgan E. EOP/WHO [Morgan.E.Bedan@who.eop.gov]; Berger, Sherri (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2b1ac8b1b9ba4abe8ef7b1d7abcd8d71-HHS-sob8-cd]; Birmingham, John (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3f23d4114514e90908a9928c8ce526e-HHS-uvk7-cd]; Blackford, Carol W (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7dc338b24154229bd381935f207cb43-HHS-Carol.B]; Bright, Rick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3bec03ac81843dab3ad88c0dd5013c1-HHS-Rick.Br]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9baf245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Ceballos, Kelly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68a916cfd4324e8bbe678c21d69a25e3-HHS-Kelly.C]; Chang, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=306e2f56f7cf45d6afae2d8d4791dad4-HHS-William]; Clay, Matt A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1dd2be2512f44fae9f59ac4aa02820c9-HHS-Matt.Cl]; CMS EPRO [EPRO@cms.hhs.gov]; Colf, Leremy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0013094ee1b4468a880d30da212ca7e6-HHS-Leremy.]; DeBord, Kristin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=317f1c057de7488189dfde7a56487c1d-HHS-Kristin]; Disbrow, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0265d217b2344c6bbbaad0cbb2f0c6a-HHS-Gary.Di]; Dreyzehner, John J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5f88b9bbd064adbb136f6769343ea6f-HHS-pwn3-cd]; Elvander, Erika (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e95f3e9a68a641e7bfd7ba7dae325e8f-HHS-Erika.E]; Espinosa, Gregorio (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e58a1f33cc27486a9b7b2c8a789ed328-HHS-Gregori]; Fernandez, Jose A (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f9ce43e810f43a0b1ff03a6a5d6d542-HHS-Jose.Fe]; Finne, Kristen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0145396d76a45f0aa05b0beaeff76db-HHS-Kristen]; Foley, Diane (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9c12678c4be4b03a2ec404a221c4ed8-HHS-Diane.F]; Giroir, Brett (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee4c4234d3834c77a4a1a7b1a7c176a2-HHS-Brett.G]; Gregg, William J (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f1ed1ebb891e44e8a073380a23746f82-HHS-hie6-cd]; Grigsby, Garrett G (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f75fca9d96c468eaf6545c6f5807057-HHS-Garrett]; Haddad, Carla (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8627be6986b64424883e696551c54187-HHS-Carla.H]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Hittle, Matthew (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8372c80ded364f19bedb4a769a5f5be09-HHS-Matthew]; Hoelscher, Douglas

(who.eop.gov) [Douglas.L.Hoelscher@who.eop.gov]; Imbriale, Samuel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8833a4896f4e4d0d86bfec7b280b7bc-HHS-Samuel.]; Johnson, Lynn (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c34079055ecd40efadb6a9df448ddce1-HHS-Lynn.Jo]; Johnson, Robert (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c7eb3a419464ea2917f9d1e3f6e57a4-HHS-Robert.]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Kadlec, Robert P (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70539a2f88924cc8913781ea74278b12-HHS-Robert.]; Kerr, Lawrence (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0920fe6d7b54496b84446fee6a21ddea-HHS-Lawrenc]; Knutson, Donna B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b32325773ad34634bc636b798b0efa97-HHS-dbk2-cd]; Kouzoukas, Demetrios (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87cab5d1c3fe48409195c03dd897988d-HHS-Demetri]; Lambert, Linda (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0ffb5d0ecbf476f827232a2e04f7c17-HHS-Linda.L]; Lekan, Scott M (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91c2aad321e84326981d5cf5d1609a84-HHS-Scott.L]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Levine, Cheryl (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2987e09098d840738cb067c49944e96f-HHS-Cheryl.]; Mair, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Maples, David L (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=47e6281952984095b3359c680e0387b9-HHS-idr0-cd]; Marks, Caryn L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e8a41c617994afa80efdda08b4c6053-HHS-Caryn.M]; Marston, Hilary D (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=87f32347b819459fb55d2b7e2bacc5eb-HHS-hilary.]; McCreary, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33bccf04199d4fd6948f0b933ce1623e-HHS-Kenneth]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; McNellis, Robert (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9f3b8126bb24c168a076cf658674f77-HHS-Robert.]; Meyers, David (AHRQ) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc5ffc86eebf47d0960fd7c6f3970896-HHS-David.M]; Monroe, Johnathan (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=444fb883930644c5bbeabe0e21ba0054-HHS-Johnath]; Moudy, Robin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad66e2f809804b82b5f35f68d60fbde4-HHS-Robin.M]; Orsega, Susan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63ed25c8067c4b838dbb689460ce0486-HHS-Susan.O]; OS Secretarys Operations Center [hhs.soc@hhs.gov]; Parker, Jim (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0601902140f426e9c5a139f7134a3c5-HHS-Jim.Par]; Patel, Anita (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c06ec0295ce4ea4985d72c66e086749-HHS-bop1-cd]; Payne, Skip (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f17ed2510b14830bf96ab774035966f-HHS-Skip.Pa]; Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]; Phillips, Sally (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1cb037be9832427da73afb313d34e243-HHS-Sally.P]; Pollard, Ashton (OS)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0eba064633c94d69ac56385c0972e3da-HHS-Ashton.]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Russo, Joseph (who.eop.gov) [Joseph.H.Russo@who.eop.gov]; Saxon, Bobby (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bb2f7db34bca4aae81a574127155ab0f-HHS-Bobby.S]; Schwartz, Erica (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=440146143d6a4020a4860bf0ad52edc1-HHS-Erica.S]; Seiler, Brittney J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bec759d8a37149dd9a94b730ff725a9b-HHS-Brittne]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; SOC Information Management Section Chief (OS/ASPR) [SOC.IM@hhs.gov]; Sprow, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64f37b83ba664226b72bbc0193dd5fff-HHS-Kyle.Sp]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Tate, Anna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b7f2e4ef1bc4e4a907d25facaafc3db-HHS-Anna.Ta]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Valentine, Steven (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80fb5b9a36fc48438ba1af4a17b63af4-HHS-Steven.]; Wallace, Rodney (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2814cd3aa9043f8bf8fc4490b6b98a-HHS-Rodney.]; Wong, Diana (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=387d66db69b24af09a2781b671bb1871-HHS-Diana.W]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebdddde-HHS-Kyle.Ze]

CC: Perdue, Christopher (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98e99090eb15457cb2d962a032e90466-HHS-Christo]

Subject: Daily guidance update

Attachments: 03102020_GuidanceUpdateFinal.pdf

Good afternoon everyone,

Here is today's COVID-19 daily guidance update. As always, if you see something that needs to be changed or want to add something, please do not hesitate to contact myself or CAPT Perdue.

Note the guidance from CDC about dialysis that was discussed in today's meeting is included.

This guidance update is being sent out to the HHS PMO list and others by request.

Very respectfully,
Will

William Farmer, MS

Presidential Management Fellow - Program Analyst
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements
Division of Requirements

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Office: (202) 205-1435 | Mobile: (b)(6)
william.farmer@hhs.gov | www.phe.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/11/2020 8:04:13 PM
To: Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Caligui, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: diagnostic statement--for urgent review
Attachments: reagent issue draft_3.11.20_245pm.docx

See minor revision for consideration. I agree with Erika's comments. Does Suzanne Schwartz need to lay eyes on it?

Thanks,

Denise

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 4:49 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: diagnostic statement--for urgent review

Just a couple of comments.

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 11, 2020 4:29 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Caligui, Laura <Laura.Caligui@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: diagnostic statement--for urgent review

Currently in HHS clearance, appreciate any flags or concerns! Thanks!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk_301.348.1956

(b)(6)
stephanie.caccomo@fda.hhs.gov

From: OS Secretarys Operations Center [hhs.soc@hhs.gov]
Sent: 3/12/2020 9:02:17 AM
To: OS Secretarys Operations Center [hhs.soc@hhs.gov]
Subject: COVID-19 Morning CDC Update 12Marr20

COVID-19 Response update Mar 12, 2020
INTERNAL - NOT FOR FURTHER DISTRIBUTION

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Very Respectfully,

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
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Sent: 3/12/2020 3:23:59 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: COV-Supply Chain Coordination Working Group

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the (b)(5)

(b)(5)

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Thursday, March 12, 2020 3:04 PM
To: Eric.Rollison (b)(6); Glenn, Robert (b)(6); mark.fleming (b)(6); david.wade (b)(6); Polowczyk, John P RADM USN JS J4 (USA (b)(6); OBRIEN, Kristina M SES JS J4 (USA (b)(6); Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA (b)(6); LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA (b)(6); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA (b)(6); thomas.j.browning (b)(6); william.t.viar (b)(6); Brown, Christopher K. - OSHA (b)(6); Glasser,J (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) (b)(6); Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal) <EBartosh@doc.gov>; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA (b)(6); Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Davis, May M. EOP/WHO (b)(6); Honeycutt, Maria G. EOP/OSTP (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Goel, Andrea L. EOP/OMB (b)(6); Chafin, Kelly B. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Butterfield, Nicholas W. EOP/WHO

(b)(6) Abbott, Christopher J. EOP/WHO (b)(6)
Farquharson, Christine E. EOP/OMB (b)(6) Carter, Hillary H. EOP/NSC
(b)(6) Crozer, William F. EOP/WHO (b)(6) Garufi, Marc A.
EOP/OMB (b)(6) Baehr, James S. EOP/WHO (b)(6) Merkel, Theo W.
EOP/WHO (b)(6) Blum, Mathew C. EOP/OMB (b)(6)
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(Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA) (b)(6); Dragseth, John
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(b)(6) Scott, Heather (b)(6) Zapata, Carmen
(b)(6) Kroese, Daniel (b)(6) Diana, Kevin
(b)(6) Ahr, Daniel (b)(6) Phillips, Sally (OS) <Sally.Phillips@hhs.gov>;
Rausch, John T CIV OSD OUSD A-S (b)(6) Wurst, Nathan J CTR OSD OUSD A-S (USA
(b)(6) Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA (b)(6)
Wilkinson, David (b)(6) Armstrong, Sue E (b)(6)
S CGRCU (b)(6) Walrod, Margaret H (Beijing) (b)(6) PRUE, ANGELA (CTR)
(b)(6) Pillai, Satish K (CDC) <vig8@cdc.gov>; Stevens, Kathleen E
(b)(6); Dole, Mark J COL USARMY OSD HA (USA) (b)(6)
Jesse.Baker@treasury.gov; Ashok.Pinto@treasury.gov; Anderson, Jacob (b)(6) Alexander,
Christopher (b)(6) Brown, Gregory (OST) <Gregory.Brown@dot.gov>;
Abigail.Demopoulos@treasury.gov; Sappenfield, Christine A (b)(6) Powers, Billy
(b)(6); Joseph.Clark2@treasury.gov; DL NSC Supply Chain (b)(6)

Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) (b)(5) Tomorrow's
meeting of the SCCWG will be cancelled (b)(5)

Path forward for the SCCWG

(b)(5)

Thanks,
Seth.

-----Original Appointment-----

From: Jonas, Seth H. EOP/NSC

Sent: Wednesday, February 26, 2020 3:15 PM

To: Jonas, Seth H. EOP/NSC; Eric.Rollison (b)(6) Glenn, Robert; mark.fleming (b)(6)
david.wade (b)(6) Polowczyk, John P RADM USN JS J4 (USA; OBRIEN, Kristina M SES JS J4 (USA; Kless, David
Ronald SES DLA LOGISTICS OPERATIONS (USA; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS
(USA; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA; thomas.j.browning (b)(6)
william.t.viar (b)(6) Brown, Christopher K. - OSHA; GlasserJL (b)(6); donna.o'berry@dot.gov;
S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov;
Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA; Marston, Hilary (NIH/NIAID) [E; Heather.Trew@treasury.gov;
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Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bop1@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA;

Brooke.Courtney@fda.hhs.gov

Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA; Wurst, Nathan J CTR OSD OUSD A-S (USA; Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA; Wilkinson, David; Armstrong, Sue E; S_CGRUCU (b)(6) Walrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vig8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL USARMY OSD HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopoulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov

Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecon (202)395-6392,, (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

Sent: 3/12/2020 3:32:23 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: COV-Supply Chain Coordination Working Group

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting?

(b)(5)

(b)(5)

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the

(b)(5)

(b)(5)

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC
Sent: Thursday, March 12, 2020 3:04 PM

(b)(6)

To: Eric.Rollison (b)(6); Glenn, Robert (b)(6); mark.fleming (b)(6); david.wade (b)(6); Polowczyk, John P RADM USN JS J4 (USA (b)(6); OBRIEN, Kristina M SES JS J4 (USA (b)(6); Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA (b)(6); LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA (b)(6); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA (b)(6); thomas.j.browning (b)(6); william.t.viar (b)(6); Brown, Christopher K. - OSHA <Brown.Christopher.K@dol.gov>; GlasserJ (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) (b)(6); Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal <EBartosh@doc.gov>; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA (b)(6); Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
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Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

(b)(5) Tomorrow's meeting of the SCCWG will be cancelled in (b)(5)

Path forward for the SCCWG

(b)(5)

(b)(5)

Thanks,
Seth.

-----Original Appointment-----

From: Jonas, Seth H. EOP/NSC

Sent: Wednesday, February 26, 2020 3:15 PM

To: Jonas, Seth H. EOP/NSC; Eric.Rollison; (b)(6) Glenn, Robert; (b)(6)
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Brooke.Courtney@fda.hhs.gov

Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO;
Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L.
EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC;
Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary
H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO;
Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov;
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Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST);
Abigail.Demopoulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov

Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecon (202)395-6392, (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/12/2020 3:33:22 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Response requested

Before we ask for you to continue – do you have time on your calendar and do you want to attend/participate in these meetings? Okay with MM?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting? Brooke is the one that understands this and is a part of it. A/S level is stretched thin. Would like to understand why they are elevating.

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the NSC Supply Chain Coordination WG is transitioning to become a PCC. By tomorrow (Friday, 03/13/2020) COB, we need to reconfirm who the principal member will be for FDA. Generally, PCCs should be attended at the Assistant Secretary level, so it seems to make sense for one of you to be the new principal. However, I'm happy to help support your efforts on this moving forward and have TS clearance if you were to ever need extra coverage.

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Thursday, March 12, 2020 3:04 PM
To: (b)(6); Glenn, Robert (b)(6); (b)(6); Polowczyk, John P RADM USN JS J4 (USA (b)(6); OBRIEN, Kristina

M SES JS J4 (USA) (b) (6) Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA
(b) (6) LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA
(b) (6); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA
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<Brown.Christopher.K@dol.gov>; (b) (6) donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew
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<Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>;
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OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A
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Lauren C. EOP/NSC (b) (6) Butterfield, Nicholas W. EOP/WHO
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Farquharson, Christine E. EOP/OM (b) (6) Carter, Hillary H. EOP/NSC
(b) (6) Crozer, William F. EOP/WHC (b) (6) Garufi, Marc A.
EOP/OMB (b) (6) Baehr, James S. EOP/WHO (b) (6) Merkel, Theo W.
EOP/WHC (b) (6) Blum, Mathew C. EOP/OMB (b) (6)
jon.krohmer@dot.gov; Olszowka, Adam R (Beijing) (b) (6); david.short@dot.gov; Dubray, Michael R
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Abigail.Demopoulos@treasury.gov; Sappenfield, Christine A (b) (6) Powers, Billy
(b) (6) Joseph.Clark2@treasury.gov; DL NSC Supply Chain (b) (6)
Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow's meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. By

tomorrow (Friday, 03/13/2020) COB, could you please reconfirm who the principal member is for your agency. Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

-----Original Appointment-----

From: Jonas, Seth H. EOP/NSC

Sent: Wednesday, February 26, 2020 3:15 PM

To: Jonas, Seth H. EOP/NSC; (b)(6) Glenn, Robert (b)(6)

(b)(6) Polowczyk, John P RADM USN JS J4 (USA); OBRIEN, Kristina M SES JS J4 (USA); Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA); LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA); (b)(6)

(b)(6) Brown, Christopher K. - OSHA; GlasserJL@state.gov; donna.o'berry@dot.gov; S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov; Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA); Marston, Hilary (NIH/NIAID) [E]; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal); Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bo11@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA); Brooke.Courtney@fda.hhs.gov

Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA); Wurst, Nathan J CTR OSD OUSD A-S (USA); Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA); Wilkinson, David; Armstrong, Sue E; S.CGRCU@groups.state.gov; Walrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vigg8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL USARMY OSD HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopolulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov

Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecon (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

From: June Wasser [REDACTED] (b)(6)]
Sent: 3/12/2020 3:44:25 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Re: rtPCR testing Question

Thanks so much!

Sent from my iPhone

On Mar 12, 2020, at 3:42 PM, Hinton, Denise <denise.hinton@fda.hhs.gov> wrote:

Hi June! I hope you are well. Yes – <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/how-submit-pre-eua-vitro-diagnostics-fda>.

Let me know if she runs into a roadblock and I'll try to make the direct connection.

Note – today the FDA launched a diagnostics specific 24/7 call center starting at 1200 today. It is being manned by PHS officers that are trained up on specifics to what is happening with COVID-19 on the lab and diagnostics front.

Those needing assistance can call 1-888-INFO FDA (463-6332) or email COVID19DX@fda.hhs.gov.

Thanks,

Denise

From: June Wasser [REDACTED] (b)(6)
Sent: Thursday, March 12, 2020 1:43 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: rtPCR testing Question

Sorry that's [REDACTED] (b)(4)

Sent from Mail for Windows 10

From: June Wasser
Sent: Thursday, March 12, 2020 1:41 PM
To: Hinton, Denise
Subject: rtPCR testing Question

Hi Denise,

I hope you are well and I suspect very busy so I'll keep this short. A colleague of mine wants to know (and asked for my help facilitating if possible) how to expedite an Emergency Use Authorization so that the [REDACTED] (b)(4) [REDACTED] (b)(4) can provide COVID-19 testing and not have to wait for CDC test kits. Do you have any advice or contacts to help answer or support such a request?

Much appreciated and as always sending you my best wishes.

June

Sent from Mail for Windows 10

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/12/2020 3:50:46 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: COV-Supply Chain Coordination Working Group

Denise, I'm sorry I didn't reply to your question below. I've been on calls much of the afternoon so have only a few updates (not all high level):

(b)(5)

From: Courtney, Brooke
Sent: Thursday, March 12, 2020 3:32 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: COV-Supply Chain Coordination Working Group

I don't have additional details, but let me see if I can get in touch with Seth now to find out more.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting? Brooke is the one that understands this and is a part of it. A/S level is stretched thin. Would like to understand why they are elevating.

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the NSC Supply Chain Coordination WG is transitioning to become a PCC. By tomorrow (Friday, 03/13/2020) COB, we need to reconfirm who the principal member will be for FDA. Generally, PCCs should be attended at the Assistant Secretary level, so it seems to make sense for one of you to be the new principal. However, I'm happy to help support your efforts on this moving forward and have TS clearance if you were to ever need extra coverage.

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Thursday, March 12, 2020 3:04 PM
To: (b)(6); Glenn, Robert <robert.glenn@fema.dhs.gov> (b)(6); (b)(6); Polowczyk, John P RADM USN JS J4 (USA) (b)(6); O'BRIEN, Kristina M SES JS J4 (USA) (b)(6); Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA) (b)(6); LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA) (b)(6); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA) (b)(6); Brown, Christopher K. - OSHA <Brown.Christopher.K@dol.gov> (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal) <EBartosh@doc.gov>; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bop1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA) (b)(6); Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Davis, May M. EOP/WHO (b)(6); Honeycutt, Maria G. EOP/OSTP (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHQ (b)(6); Goel, Andrea L. EOP/OMB (b)(6); Chafin, Kelly B. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Abbott, Christopher J. EOP/WHO (b)(6); Carter, Hillary H. EOP/NSC (b)(6); Crozer, William F. EOP/WHO (b)(6); Garufi, Marc A. EOP/OMB (b)(6); Baehr, James S. EOP/WHO (b)(6); Merkel, Theo W. EOP/WHO (b)(6); Blum, Mathew C. EOP/OMB (b)(6); jon.krohmer@dot.gov; Olszowka, Adam R (Beijing) (b)(6); david.short@dot.gov; Dubray, Michael R (Wuhan) (b)(6); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Benjamin Carlson <Benjamin.Carlson@trade.gov>; Bedan, Morgan E. EOP/WHO (b)(6); LaBrecque, Michael F

(Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); (b)(6) Dragseth, John
(b)(6) Lerner, Andrea M (NIH) <andrea.lerner@nih.gov>; KEENE, CHRISTOPHER
(b)(6) Scott, Heather; (b)(6) Zapata, Carmen
(b)(6) Kroese, Daniel; (b)(6) Diana, Kevin
(b)(6) Ahr, Danie; (b)(6) Phillips, Sally (OS) <Sally.Phillips@hhs.gov>;
Rausch, John T. CIV. OSD OJJSN A-S (USA); (b)(6) Wurst, Nathan J CTR OSD OUSD A-S (USA
(b)(6) Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA); (b)(6)
Wilkinson, David; (b)(6) Armstrong, Sue E; (b)(6)
(b)(6) Walrod, Margaret H (Beijing); (b)(6); PRUE, ANGELA (CTR)
(b)(6); Pillai, Satish K (CDC) <vig8@cdc.gov>; Stevens, Kathleen E
(b)(6) Dole, Mark J COL USARMY OSD HA (USA); (b)(6)
Jesse.Baker@treasury.gov; Ashok.Pinto@treasury.gov; Anderson, Jacob; (b)(6) Alexander,
Christopher; (b)(6); Brown, Gregory (OST) <Gregory.Brown@dot.gov>;
Abigail.Demopoulos@treasury.gov; Sappenfield, Christine A; (b)(6) Powers, Billy
(b)(6) Joseph.Clark2@treasury.gov; DL NSC Supply Chain; (b)(6)
Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow's meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. **By tomorrow (Friday, 03/13/2020) COB**, could you please reconfirm who the principal member is for your agency. Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

-----Original Appointment-----

From: Jonas, Seth H. EOP/NSC

Sent: Wednesday, February 26, 2020 3:15 PM

To: Jonas, Seth H. EOP/NSC; (b)(6); Glenn, Robert; (b)(6)

(b)(6); Polowczyk, John P RADM USN JS J4 (USA; OBRIEN, Kristina M SES JS J4 (USA; Kless, David
Ronald SES DLA LOGISTICS OPERATIONS (USA; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS
(USA; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA; (b)(6);
(b)(6); Brown, Christopher K. - OSHA; (b)(6); donna.o'berry@dot.gov;
S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov;
Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA; Marston, Hilary (NIH/NIAID) [E; Heather.Trew@treasury.gov;
Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal;
Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bop1@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA;
Brooke.Courtney@fda.hhs.gov

Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO;
Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L.
EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC;
Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary
H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO;
Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov;
Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov;

amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA; Wurst, Nathan J CTR OSD OUSD A-S (USA; Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA; Wilkinson, David; Armstrong, Sue E; S CGRCU@groups.state.gov; Walrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vigg8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL USARMY OSD HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopoulos@treasurv.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov

Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Teleco: (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/12/2020 6:27:15 PM
To: Araojo, Richardae [Richardae.Araojo@fda.hhs.gov]
Subject: FW: COVID-19 Daily Guidance Update for 12Mar20
Attachments: 03122020_GuidanceUpdateFinal.pdf

From: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Sent: Thursday, March 12, 2020 5:47 PM
To: OS Secretarys Operations Center <hhs.soc@hhs.gov>
Subject: COVID-19 Daily Guidance Update for 12Mar20

UNCLASSIFIED // FOR OFFICIAL USE ONLY

Good afternoon all,

Please see the attached COVID-19 Daily Guidance Update for 12Mar20. If you have any questions, comments or concerns, please contact CAPT Perdue.

This notification was sent to the COVID-19 PMO distribution list.

Very Respectfully,

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) (b)(6)
Fax: 800-514-4256
Email: hhs.soc@hhs.gov



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From: OS Secretarys Operations Center [hhs.soc@hhs.gov]
Sent: 3/12/2020 6:29:18 PM
To: OS Secretarys Operations Center [hhs.soc@hhs.gov]
Subject: HHS International SPOTREP: COVID-19 (Update #157)
Attachments: COVID-19 SLB 12Mar20 FINAL.pdf

UNCLASSIFIED // FOR OFFICIAL USE ONL

HHS International SPOTREP: COVID-19 (Update #157)

Source: Interagency

What: Please see the attached COVID-19 Senior Leader Brief for **12Mar20** for more information.

When: **12Mar20 1830ET**

Where: International

Why: CIR: Disease – International

Actions/Follow-Up: The SOC will continue to monitor this incident and report as needed. *This message was distributed to the 2019 nCoV IMT, 2019 nCoV Interagency, 2019 nCoV IST, 2019 nCoV Senior Leadership Distribution Lists.*

Prepared by: Brian Pittman, Watch Officer

Approved by: Brandon W. Britton, Senior Watch Officer

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) (b)(6)
Fax: 800-514-4256
Email: hhs.soc@hhs.gov



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From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/12/2020 9:39:21 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: DRAFT WHTF Briefing 03.12.2020.docx
Attachments: DRAFT WHTF Briefing 03.12.2020.docx

Attached are talking points and information from today. Will send earlier tomorrow.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/12/2020 11:12:45 PM
To: Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Response requested

Thanks for the information Brooke. You're well-suited to represent us at the meeting as you'll receive information from each center in the WG meetings. Please let us know how we can best support you.

Best,

Denise

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 11:04 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: RE: Response requested

Hi Keagan and Denise,

I just spoke with Seth Jonas from the SCCWG. The NSC is still working to finalize the administrative aspects, but here's what they have so far:

(b)(5)

Thanks,
Brooke

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting? Brooke is the one that understands this and is a part of it. A/S level is stretched thin. Would like to understand why they are elevating.

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the NSC Supply Chain Coordination WG is transitioning to become a PCC. By tomorrow (Friday, 03/13/2020) COB, we need to reconfirm who the principal member will be for FDA. Generally, PCCs should be attended at the Assistant Secretary level, so it seems to make sense for one of you to be the new principal. However, I'm happy to help support your efforts on this moving forward and have TS clearance if you were to ever need extra coverage.

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC (b)(6)
Sent: Thursday, March 12, 2020 3:04 PM
To: (b)(6); Glenn, Robert <robert.glenn@fema.dhs.gov> (b)(6)
(b)(6); Polowczyk, John P. RADM USN JS J4 (USA) (b)(6); OBRIEN, Kristina M S ES JS J4 (USA) (b)(6); Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA) (b)(6); LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA) (b)(6); Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA) (b)(6); Brown, Christopher K. - OSHA <Brown.Christopher.K@dol.gov> (b)(6); donna.o'berry@dot.gov; S60.Policy@dot.gov; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal) <EBartosh@doc.gov>; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <bp1@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA) (b)(6); Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Davis, May M. EOP/WHO (b)(6); Honeycutt, Maria G. EOP/OSTP (b)(6); Sinclair, Michael R. EOP/NSC (b)(6); Hoelscher, Douglas L. EOP/WHO (b)(6); Goel, Andrea L. EOP/OMB (b)(6); Chafin, Kelly B. EOP/NSC (b)(6); Ferro, Phil J. EOP/NSC (b)(6); Fabina, Lauren C. EOP/NSC (b)(6); Butterfield, Nicholas W. EOP/WHO (b)(6); Abbott, Christopher J. EOP/WHO (b)(6); Farquharson, Christine E. EOP/OMB (b)(6); Carter, Hillary H. EOP/NSC (b)(6); Crozer, William F. EOP/WHO (b)(6); Garufi, Marc A. EOP/OMB (b)(6); Baehr, James S. EOP/WHO (b)(6); Merkel, Theo W.

EOP/WHO (b)(6) Blum, Mathew C. EOP/OMB (b)(6)
jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); (b)(6); david.short@dot.gov; Dubray, Michael R
(Wuhar); (b)(6); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Benjamin Carlson
<Benjamin.Carlson@trade.gov>; Bedan, Morgan E. EOP/WHO (b)(6); LaBrecque, Michael F
(Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); (b)(6); Dragseth, John
(b)(6); Lerner, Andrea M (NIH) <andrea.lerner@nih.gov>; KEENE, CHRISTOPHER
(b)(6); Scott, Heather (b)(6); Zapata, Carmen
(b)(6); Kroese, Daniel (b)(6); Diana, Kevin
(b)(6); Ahr, Danie (b)(6); Phillips, Sally (OS) <Sally.Phillips@hhs.gov>;
Rausch, John T CIV OSD OUSD A-S (USA); (b)(6); Wurst, Nathan J CTR OSD OUSD A-S (USA
(b)(6); Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA); (b)(6)
Wilkinson, David; (b)(6); Armstrong, Sue E; (b)(6)
(b)(6); Walrod, Margaret H (Beijing) <(b)(6)>; PRUE, ANGELA (CTR)
(b)(6); Pillai, Satish K (CDC) <vig8@cdc.gov>; Stevens, Kathleen E
(b)(6); Dole, Mark J COL USARMY OSD HA (USA); (b)(6);
Jesse.Baker@treasury.gov; Ashok.Pinto@treasury.gov; Anderson, Jacob (b)(6); Alexander,
Christopher (b)(6); Brown, Gregory (OST) <Gregory.Brown@dot.gov>;
Abigail.Memopoulos@treasury.gov; Sappenfield, Christine A; (b)(6); Powers, Billy
(b)(6); Joseph.Clark2@treasury.gov; DL NSC Supply Chain (b)(6)

Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow's meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. **By tomorrow (Friday, 03/13/2020) COB**, could you please reconfirm who the principal member is for your agency. Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

-----Original Appointment-----

From: Jonas, Seth H. EOP/NSC

Sent: Wednesday, February 26, 2020 3:15 PM

To: Jonas, Seth H. EOP/NSC; (b)(6); Glenn, Robert; (b)(6);
(b)(6); Polowczyk, John P RADM USN JS J4 (USA; OBRIEN, Kristina M SES JS J4 (USA; Kless, David
Ronald SES DLA LOGISTICS OPERATIONS (USA; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS
(USA; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA); (b)(6)
(b)(6); Brown, Christopher K. - OSHA; (b)(6); donna.o'berry@dot.gov;
S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov;
Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA; Marston, Hilary (NIH/NIAID) [E; Heather.Trew@treasury.gov;
Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal;
Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bop1@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA;
Brooke.Courtney@fda.hhs.gov

Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO;
Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L.
EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC;

Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA; Wurst, Nathan J CTR OSD OUSD A-S (USA; Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA; Wilkinson, David; Armstrong, Sue E; (b)(6) Walrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vig8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL USARMY OSD HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopoulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov

Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecon (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available

Sent: 3/13/2020 2:53:27 PM
To: Hinton, Denise [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=HINTOND]
Subject: COVID19 Readiness

Don Demers

(b)(5)

Pillai

(b)(5)

Denise

RADM Denise M. Hinton
Assistant Surgeon General
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/13/2020 7:14:30 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: News from call with McKesson

Thanks, Denise!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, March 13, 2020 7:09 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: News from call with McKesson

No apology necessary. We prefer you represent – thank you!

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 6:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: News from call with McKesson

Also, I'm sorry I've been tied up today and haven't yet

(b)(5)

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, March 13, 2020 6:40 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: News from call with McKesson

I hope we all do! Thank you

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 6:39 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: News from call with McKesson

Thanks, and I hope you can get some downtime this weekend!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, March 13, 2020 6:25 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FW: News from call with McKesson

From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Sent: Friday, March 13, 2020 5:40 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Subject: News from call with McKesson

Good afternoon: You asked for news from my call with McKesson today. CDRH and Brooke Courtney are also informed.

Early Surveillance of Emerging Shortages

(b)(5)

Tests and Diagnostics

1. Nasopharyngeal swabs and vials (transportation devices) for complementary testing are in shortage-- there is "no inventory" and they are under "severe allocation", i.e., seller-imposed quotas. **The shortage derives from conventional flu testing but it implies there may be no capacity to do additional COVID testing, because these swabs and vials are essential for such testing.** Orders are running about double last year's levels. (b)(5)

(b)(5)

(b)(5)

2. Rapid Flu and Strep tests: Currently supplies are low. They are concerned that if these tests become required before COVID-19 testing, then supplies would be inadequate.

PPE

3. N95 Masks – Currently supplies are low. They are directing customers to HHS to get the 3M product, (b)(5)

(b)(5)

(b)(5)

4. Isolation gowns – There is "no inventory". (b)(5)

Already have a shortage of higher-level protection gowns (due to prior recall before COVID outbreak), but basic gowns available.

5. Gloves – Still have Nitrile gloves in stock, but concerned that if nursing homes switch to a higher level of protection, there would not be enough of those gloves

Drugs

6. IV solutions that are not produced in the U.S. Manufacturers are starting to limit sales, so these are already on allocation.

Best regards,

-Randy

202 308 0104

Sent: 3/13/2020 8:09:42 PM
To: Stenzel, Timothy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e181c337cf1d429bae363600706a5fc4-Timothy.Ste]
Subject: Summary re: Laser Inactivation of Viruses
Attachments: Vaccines for Corona Virus Summary.pdf

Dear Tim,

Please find attached a summary of [REDACTED] (b)(4) [REDACTED] Feel reach out to him at the number or email listed below for further information.

[REDACTED] (b)(4) [REDACTED]

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.

Best,
Denise

From: Thomas, Audrey A [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E1250E3B21344CE89BD561FF8BAE53A-THOMASA]
Sent: 3/14/2020 7:02:33 AM
To: Wilson, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a78919ec52b7440e94f5928758847404-wilsonc]; Barratt, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7a14bd5dcfd4121849b18beffcebbdb-BARRATTR]; Mendrick, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2be78d4cfe4c8fa2685b38cbdd6e25-DMendrick]; Kwan, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c10cdb276014c4dae0b399f86ba64ff-Jonathan.Kw]; Braunstein, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4eb429abb54b56ae58a84d1c0077ba-BraunsteinE]; Nugent, Bridget [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=304aba05001b40518bc37dce94044ff8-Bridget.Nug]; Ruiz, Juan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b773dc886c0d4dfba2ee6919f5cc80e5-Juan.Ruiz]; Johanson, Elaine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Bright, Roselie A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4eef60c88912461ca085bcb876d3b45c-RXB]; Patel, Keyur [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70077d1043dc4a8bb0ef774865deb60f-Keyur.Patel]; Schneider, Julie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b938530b11846a29dca7d031cdf3d34-Julie.Schne]; Vasisht, Kaveeta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=829ef402d6284b4aab60db92ebada1dd-VASISHTK]; Lee, Christine (OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46b2c2861a86482589389aee84448588-LEECHRI]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Margerrison, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12386cee44f645b69f7215d42b265d70-Edward.Marg]; Saha, Anindita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f66659d5a8a4c6f8ffdbddccc7d312-AXS]
CC: Blumkemelor, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7676a976c93642f985adabb1f7ef2db8-Donna.Blumk]; Zinn, Rebekah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28f2489f571f4117971b764ce05a43a8-Rebekah.Zin]; Chada, Kinnera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6477a3fe02e40d7a6d7db5c40f92ba5-ChadaK]; Smith, Tara (CDRH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f75e433d7e564d7e848c5284e3921326-Tara.Smith]; 'joseph.ross@yale.edu' [joseph.ross@yale.edu]; shah.nilay@mayo.edu; Ritchie, Jessica [jessica.ritchie@yale.edu]; Ciaccio, Laura [laura.ciaccio@yale.edu]
Subject: RE: COVID19
Attachments: Mayo Clinic CERSI - COVID-19 Related Resources 031320.docx

FYI. Please find attached a one-pager from Mayo Clinic CERSI on Mayo's resources related to COVID-19. If you would like to connect with Mayo Clinic, please contact Nilay Shah at shah.nilay@mayo.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A

Sent: Monday, March 09, 2020 3:51 PM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>

Subject: RE: COVID19

FYI. Please find attached a one-pager from Yale University CERSI on Yale's resources related to COVID-19. If you would like to connect with the Yale University, please contact Joe Ross at joseph.ross@yale.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A

Sent: Sunday, March 08, 2020 7:03 PM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Russ B Altman <Russ.Altman@stanford.edu>; 'Giacomini, Kathy' (<Kathy.Giacomini@ucsf.edu> <Kathy.Giacomini@ucsf.edu>); 'Lin, Lawrence' (<Lawrence.Lin@ucsf.edu> <Lawrence.Lin@ucsf.edu>); Friciello, Maria (<Maria.Friciello@ucsf.edu> <Maria.Friciello@ucsf.edu>)

Subject: RE: COVID19

FYI. Russ Altman reached out to me to say that Stanford is in the middle of a crisis. They have a faculty member at the Med School that has tested positive for coronavirus. The school is moving to online classes along with other restrictions. I told Russ not to worry about my request.

I think that this will become more and more prevalent

(b)(6)

(b)(6)

Audrey

From: Thomas, Audrey A

Sent: Sunday, March 08, 2020 11:59 AM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; William Bentley <bentley@umd.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>
Subject: RE: COVID19

As requested, I have reached out to the CERSIs for information on their resources related to COVID-19. I just received a one-pager from the University of Maryland CERSI, Baltimore Campus. If you would like to connect with the University of Maryland, please contact James Polli at jpolli@rx.umaryland.edu (copied on this email).

Thanks.

Audrey Thomas

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>

Sent: Sunday, March 08, 2020 9:17 AM

To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Subject: RE: COVID19

Many thanks Audrey.

I shared with our CoV coordinator in CBER and we both think it would be great if you could reach out to each of the CERSIs with a similar request. Can't hurt to be more aware of all potentials out there.

Also, I'm assuming you are sharing the information with OCET as well.

Carolyn

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>

Sent: Sunday, March 8, 2020 7:25 AM

To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>

Subject: FW: COVID19

Importance: High

FYI. As per discussion at Thursday's Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU's resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.

Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader

UCSF-Stanford CERSI Program Official (PO)

Office of Regulatory Science and Innovation (ORSI)

Office of the Chief Scientist

Office of the Commissioner

Food and Drug Administration

10903 New Hampshire Avenue

Bldg. 1, Rm 4220

Silver Spring, MD 20903

301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>

Sent: Saturday, March 07, 2020 8:46 PM

To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>

Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: COVID19

Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins' resources that may be relevant to FDA's COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc:d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH's Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA's response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsp.h.edu

To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>

Sent: Sunday, March 15, 2020 3:36 PM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Subject: RE: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

Adding Mark, Claire, and Marcy for OCC.

Thanks,
Dinesh

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Sent: Sunday, March 15, 2020 3:31 PM

To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Subject: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

Importance: High

Hello all,

Sharing, on Stephanie's behalf, Dr. Hahn's remarks for the HHS briefing this evening on COVID testing for urgent review by 4:30 p.m. OMA tried to use as much previously cleared content as possible.

The document for concurrent review is available in SharePoint: <http://sharepoint.fda.gov/orgs/OCEA/OMA/Comms%20for%20Editing/opening%20remarks%20drive%20by%20testing.docx>

Thank you,

Michael

Michael Felberbaum
Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 (b)(6)
michael.felberbaum@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/15/2020 4:16:41 PM
To: Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Clarke, Mary Beth [Marybeth.Clarke@fda.hhs.gov]
Subject: Quick response requested: Talking Points on COVID Therapeutics/Vaccines - by 1630
Attachments: Therapeutics TPs 03152020 324pm.docx

Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/16/2020 9:22:11 AM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]
Subject: FW: 16Mar COVID-19 Operational Update Brief
Attachments: 16Mar20 - 0815ET HHS COVID-19 Operational Update Brief.pptx

Tell me if you're already receiving these.

Thanks,

Denise

HHS COVID-19 Operational Update Brief

Dial-in information: 212 (b)(6) **Passcode:** (b)(6)

Frequency: M-F

Time: 0815ET

Agenda:

- Opening Comments
- Priorities and Objectives
- Operational Activities
- Planning Activities
- Scientific Priorities
- Healthcare System
- Supply Chain
- Messaging
- Public Reaction
- Activated ESF and LNO Updates
- New Guidance and Policies
- Primary Inter/Intra-Agency Agreements
- Meeting Wrap-Up and Closing Comments

:

Prepared by:

Secretary's Operations Center

U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave., S.W.
Washington, D.C. 20201
Office: (202) 619-7800

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Email: hhs.soc@hhs.gov



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From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 3/16/2020 11:11:09 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Lenihan]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS
Attachments: Diagnostic guidance_updated policy_3.16_11am.docx

Attached is the FDA-cleared statement that's with HHS.

Michael Felberbaum

Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548
michael.felberbaum@fda.hhs.gov

(b)(6)



From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:10 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: URGENT NEED INFO ON CDRH ACTIONS

I need to get hahn talking points in 15 minutes on actions cdrh is taking

(b)(5)

(b)(5)

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/16/2020 11:36:39 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Kahn, Jeremy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b98d36d2c1f4ae795140b68de7b37f7-Jeremy.Kahn]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

(b)(5)

From: McWilliams, Carly
Sent: Monday, March 16, 2020 11:20 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

See below: taken from statement and attached are talkers from last night.

(b)(5)

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(b)(5)

(b)(5)

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Sent: Monday, March 16, 2020 11:11 AM

To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

(b)(5)

Michael Felberbaum

Senior Advisor

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration

Tel: 240-402-5548 / Cell: (b)(6)
michael.felberbaum@fda.hhs.gov



From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>

Sent: Monday, March 16, 2020 11:10 AM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura
<Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: URGENT NEED INFO ON CDRH ACTIONS

I need to get hahn talking points in 15 minutes on actions cdrh is taking [redacted] (b)(5)
[redacted] (b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/16/2020 11:56:12 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:37 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

Also latest numbers if he needs them: shout out to OL for the update.

Since March 2, over 10.4 million tests have become available for the U.S. market, including over 8.28 million tests last week alone.

Two tests had generally been performed per person up to now, but new CDC guidance generally allows just one test to be sufficient for a person not including controls.

From: McWilliams, Carly
Sent: Monday, March 16, 2020 11:20 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

See below: taken from statement and attached are talkers from last night.

Good Morning, thank you for joining today. I know there is a lot of focus and interest on what FDA is doing to combat covid 19 and specifically our work on diagnostics.

I can assure that that we have been working tirelessly throughout this coronavirus outbreak to support efforts across the government to address and mitigate this outbreak.

Those efforts include facilitating the availability and distribution of diagnostic tests, such as the updated policy we are issuing today.

- I know there has been some confusion and concern around the availability of diagnostics. It's important for the public to understand the role of diagnostics in emergencies and why this particular situation has been different than past outbreaks. And I appreciate you being on the phone today to understand what we are doing and the resources we have available to support labs and grow testing capacity.

I am going to talk specifically on the actions we are taking now:

- First, we are putting in place a policy that gives states the option to take responsibility for tests developed in their states. Similar to the action the FDA granted to the New York State Department of Health last week, states can take responsibility for overseeing tests developed and used by laboratories in their states. States can set up a system in which the state takes responsibility for authorizing such tests, and the laboratories will not engage with the FDA. The system does not need to mirror that of New York. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of FDA. Nor will these laboratories be pursuing an EUA with FDA.
- Second, we are expanding who the policy outlined in the Feb. 29 guidance applies to - the policy issued on Feb. 29 was originally applicable only to laboratories that are certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments.
- Under the update published today, the agency will not object to commercial manufacturers distributing and labs beginning using new commercially developed tests prior to FDA granting an EUA,

under certain circumstances. We are aware that numerous commercial manufacturers are developing tests for coronavirus with the intention of submitting an EUA to FDA.

- During this public health emergency, FDA does not intend to object to the distribution and use of these tests for specimen testing for a reasonable period of time after the manufacturer's validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test's performance characteristics on the manufacturer's website. FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated by the manufacturer.

- Finally, our updated policy provides recommendations for test developers who may wish to develop serological tests for use during this coronavirus outbreak. Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection. We recognize that serology tests are less complex than molecular tests and are solely used to identify antibodies, which limits their effectiveness for diagnosis; however, as stated in the updated guidance, the FDA is not objecting to the distribution and use of serology tests to identify antibodies to SARS-CoV-2 where the test has been validated, notification is provided to FDA, and warning statements are included with the tests, for example, noting the test has not been reviewed by the FDA and positive results may be due to a past or present infection with a different coronavirus strain.

FDA Support of Diagnostics

- The FDA has engaged with more than 100 test developers since the end of January, providing templates and advice about the Emergency Use Authorization process. More than 80 developers have sought our assistance with development and validation of tests they plan to bring through the EUA process.

- We are keeping frequently asked questions updated for labs and test developers, providing information on alternative sources of reagents, extraction kits, swabs and more.
- We've also set up a toll-free line, 1-888-INFO-FDA, to help labs with any questions they may have about the EUA process, our policies, or getting supplies.
- We know that people want to know the current numbers of tests in the field and how many patients are being tested. This number fluctuates daily as more and more test developers get their tests in the field and start testing patients. At this time FDA is focused on making sure tests are distributed and that test developers and labs have the materials they need to run the tests.
- The FDA continues to maintain operations 24/7 and we are here to support laboratories and test developers as they distribute tests through the country during this time of urgent need.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

Sent: Monday, March 16, 2020 11:11 AM

To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

Attached is the FDA-cleared statement that's with HHS.

Michael Felberbaum

Senior Advisor

Office of Media Affairs

Office of External Affairs

U.S. Food and Drug Administration

Tel: 240-402-9548 / Cell: (b)(6)

michael.felberbaum@fda.hhs.gov



From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>

Sent: Monday, March 16, 2020 11:10 AM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura

<Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>

Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

Subject: URGENT NEED INFO ON CDRH ACTIONS

I need to get hahn talking points in 15 minutes on actions cdrh is taking

(b)(5)

(b)(5)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/16/2020 2:35:36 PM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]
Subject: MICHAEL READ: Corona Testing

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:34 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Re: Corona Testing

Thanks Lowell. I'll get this to the WH Taskforce

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Date: March 16, 2020 at 2:32:16 PM EDT
To: COVID-19 IMG <COVID19IMG@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: FW: Corona Testing
Importance: High

All,

I received a call, and the email below, from the Food Marketing Institute (trade association for supermarkets/grocery stores). They have members who would like to offer retailer parking lots as testing sites. Can we provide them information or a point of contact?

Also, please note that FMI is hosting daily COVID-19 calls with their industry, and they have offered this forum as a way for FDA to communicate broadly with this industry, if helpful.

Best,
Lowell

From: Peter Matz (FMI) <pmat@fmi.org>
Sent: Monday, March 16, 2020 1:48 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: Corona Testing
Importance: High

Hi Lowell, as I mentioned, there is a lot of interest from FMI supermarket companies in particular re participating in the partnership announced over the weekend whereby COVID-19 testing will take place in certain retailer parking lots nationwide. The President mentioned Walmart, Target and others before requesting additional volunteers. We have several companies asking how they can learn more and offer their assistance. I understand there may be an MOU

through HHS, but I haven't seen anything so I can't be sure. Any guidance or thoughts you may have would be greatly appreciated. Thank you!

Separately, we are hosting daily COVID-19 conference calls with our industry and we have invited other groups to join as well, so pls don't hesitate if FDA ever has any updates or would like to solicit feedback on corona-related challenges or response efforts.

Again, many thanks,
Peter

Peter Matz
Director, Food & Health Policy
FMI - The Food Industry Association
Direct 202.220.0805
Cell: **(b)(6)**
www.fmi.org

From: Malais, Tanya [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
Sent: 3/16/2020 3:39:01 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: 3-16-20 COVID-19 AEG Meeting Notes
Attachments: 3-16-20 COVID-19 AEG Meeting Notes.docx

Good afternoon,

Attached are my notes from the 3/16/20 AEG meeting, which has been uploaded in the COVID-19 AEG SharePoint subsite.

Tanya E. Malais
Planning Section Chief
2019 Novel Coronavirus (nCoV) IMG
Office: 949-608-2984
Mobile: (b)(6)
Planning Section Email: 2019-nCoVFDAIMGPlanning@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/16/2020 6:00:42 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Arriving in 30 minutes!!! COVID-19: SNS import of unapproved test kits & masks

Have attachment?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, March 16, 2020 5:59 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: Arriving in 30 minutes!!! COVID-19: SNS import of unapproved test kits & masks

See below – 564B

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 5:37 PM
To: Cave, Carol <Carol.Cave@fda.hhs.gov>; Verbeten, John E. (ORA) <John.Verbeten@fda.hhs.gov>; Dixon, Ruth P <Ruth.Dixon@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Torres, Melissa A <Melissa.Torres@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Gehrman, Gayle J <Gayle.Gehrman@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Kannan, Lakshmi <Lakshmi.Kannan@fda.hhs.gov>; Dixon, Ruth P <Ruth.Dixon@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Diamond, Matthew <Matthew.Diamond@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: COVID-19: SNS import of unapproved test kits & masks

Dear Carol, John, and Ruth,

John, many thanks again to you and Gayle for your guidance on (b)(3) 42 USC 247d-6b(d)

(b)(3) 42 USC 247d-6b(d)

(b)(3) 42 USC 247d-6b(d) , (b)(4)

Additional information from the SNS about these products and shipment is attached. If you have any questions, please don't hesitate to let us know (CDRH and OCC are copied). We'll be sure to provide you with any updates we might receive. Many thanks in advance for your time.

Kind regards,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats

Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) (b)(6) cell
brooke.courtney@fda.hhs.gov

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/16/2020 6:02:28 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: donated test kits, masks
Attachments: Da An Gene Cert of CE Reg incl. Annex A02052020(1).pdf; Extraction Kit Details.pdf; Detection Kit Details.pdf

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 16, 2020 1:49 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: donated test kits, masks

From: Gorman, Susan (ASPR/SNS) <spg4@cdc.gov>
Sent: Friday, March 13, 2020 4:25 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Adams, Steven A (CDC) <saa1@cdc.gov>
Subject: RE: donated test kits, masks

Hi Brooke,
The test kit info is attached. Current shipment for test kits will be for (b)(4) and a follow on shipment in about a week for another (b)(4)

A. Flight Information

(b)(4)

B. Shipment Information

Total volume to the US: (b)(4) cubic meters

1. (b)(4)

(b)(4)

2. (b)(4)

I. (b)(4)
II. (b)(4)
III. (b)(4)

There is some other paperwork & info that will be forthcoming

Sue

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 4:08 PM
To: Gorman, Susan (ASPR/SNS) <spg4@cdc.gov>
Cc: Adams, Steven A. (ASPR/SNS) <saa1@cdc.gov>
Subject: RE: donated test kits, masks

Hi Sue,

Thank you! Do you have the manufacturer name of the test kits and do you know what type of PPE (surgical masks only? manufacturer)? I'm going to give our import leadership a heads up now.

Thanks,
Brooke

From: Gorman, Susan (ASPR/SNS) <spg4@cdc.gov>
Sent: Friday, March 13, 2020 4:04 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Adams, Steven A (CDC) <saa1@cdc.gov>
Subject: donated test kits, masks

Hi Brooke,
We expect to have the shipment information to you today – Steve will be sending it soon
Thank you
Sue

Sent: 3/16/2020 6:07:33 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: Full information FYSA re: COVID-19 SNS import of unapproved test kits & masks
Attachments: Detection Kit Details.pdf; Extraction Kit Details.pdf; (b)(4)

Sending FYSA so you have full information for reference.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 5:37 PM
Subject: COVID-19: SNS import of unapproved test kits & masks

Dear Carol, John, and Ruth,

John, many thanks again to you and Gayle for your guidance on the recent HHS Strategic National Stockpile (SNS) import question. We now have another import for the SNS that is moving fast and expected to arrive in the U.S. on March 17.

(b)(3) 42 USC 247d-6b(d)

(b)(3) 42 USC 247d-6b(d)

Additional information from the SNS about these products and shipment is attached. If you have any questions, please don't hesitate to let us know (CDRH and OCC are copied). We'll be sure to provide you with any updates we might receive. Many thanks in advance for your time.

Kind regards,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) (b)(6) (cell)
brooke.courtney@fda.hhs.gov

From: Greg Maselli [greg@117global.com]
Sent: 3/17/2020 11:48:31 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: (b)(4)
Attachments: (b)(4)

Hi Denise,

I am doing my best to track down the correct person and I don't believe there is anyone higher up than you for this.

(b)(4)

(b)(4)

(b)(4)

If you can be of assistance, let me know what I need to do or how you can help.

Thank you again and I hope to hear back from you,

Greg Maselli

From: grant stafford [grant@117global.com]
Sent: 3/17/2020 6:21:00 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
CC: Greg Maselli [greg@117global.com]
Subject: EUA for a COVID-19 IgG/IgM Rapid Test Kit
Attachments: COVID-19-Step_by_step.jpg; COVID-19-Test Kit.png; FDA_screenshot.PNG

3/17/2020 RADM Denise Hinton, Chief Scientist

Food and Drug Administration

Room 3317, Silver Spring MD 20993-0002

Dear Mrs. Hinton:

My company is a product development and manufacturing management firm located in California. We work with food and medical technology companies here, in the US and in China. We are representing a medical device company located in China who has developed a rapid COVID-19 at home test kit. This device is not yet certified with the FDA and we are seeking to have this device **COVID-19 IgG/IgM Rapid Test Kit** authorized under the Emergency Use Authorization (EUA) to import and market these kits in the United States. Below is a brief description of the device.

INTENDED USE

COVID-19 IgG/IgM Rapid Test Kit(Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/Serum/Plasma) must be confirmed with alternative testing methods and clinical findings.

This manufacturer has performed a clinical study and a white paper is available. They have products that are actively registered with the FDA. Since this device is so new, we are pending the 6-9 weeks of FDA approval. Knowing that this is an urgent situation in our country, I felt it was appropriate to contact you directly. We have several million units ready for import, but we need to make sure the approval goes through the correct channels.

We have found one other factory with a listed FDA number manufacturing a similar test. The device can be found on the FDA site (link below) and it appears to be granted under the EUA

<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm?lid=650355&lpcd=QJR>

Attached are some pictures of the device along with the step by step explanation of performing the test. We are requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the **COVID-19 IgG/IgM Rapid Test Kit** to enable the immediate importing and marketing of these devices.

I want to thank you for your service and consideration in helping us. I am seeking your assistance with navigating the authorization to import and market these kits. We are uncertain under the new regulations for EUA and the importing of medical products such as these. I found your contact when researching the COVID-19 FDA website and your authorization to Thermo Fisher Scientific, Inc. (Thermo Fisher) for their TaqPath COVID-19 Combo Kit.

How should we proceed?

Sincerely yours,

Grant Stafford

Principal,

117 Global LLC

--
Grant Stafford
grant@117global.com
(b)(6)
grant.stafford@117global.com
grant.stafford@117global.com

Sent: 3/18/2020 9:05:49 AM
To: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]
Subject: FOUO: HHS COVID19 Operational Update
Attachments: 18Mar20 - 0815ET HHS COVID-19 Operational Update Brief.pdf; 38_2019-nCoV Outbreak_FDA SITREP_17 March 2020.docx

Good morning Bill and Tucker,

Please see the attached documents for your situational awareness. Note that the Situation Report (in WORD), prepared by the Incident Management Group (IMG) has CCI and should not be shared further. The IMG is led by our Agency Incident Commander, Michael Mair.

Also, note the FDA has operationalized a diagnostics 24/7 call center. It will be manned by PHS officers that are trained up on specifics to what is happening with COVID-19 on the lab and diagnostics front.

Those needing assistance can call 1-888-INFO FDA (463-6332) or email COVID19DX@fda.hhs.gov.

Hope you find the information useful.

Best,

Denise

Sent: 3/18/2020 10:17:18 AM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]; Roberts, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b7838eab964e4ca1a7d703876d08411b-ROBERTSR]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: materials for 3/18 Internal Confidential Deliberative

Thanks for the email and it is indeed helpful to include Michael Mair as the IMG Agency Incident Coordinator on these discussions, as much as possible, for situational awareness and in order to facilitate responses with the Center's lead.

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 10:09 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: materials for 3/18 Internal Confidential Deliberative

No need to apologize ! These are exceptional times . We all got on a call and sorted this out.

Patrizia

From: Mair, Michael <Michael.Mair@fda.hhs.gov>

Date: March 18, 2020 at 9:31:06 AM EDT

To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: RE: materials for 3/18 Internal Confidential Deliberative

Apologies on process – I was not attempting to work this issue here

(b)(5)

(b)(5)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

Sent: Wednesday, March 18, 2020 9:23 AM

To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: RE: materials for 3/18 Internal Confidential Deliberative

(b)(5)

Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>

Date: March 18, 2020 at 9:14:26 AM EDT

To: Mair, Michael <Michael.Mair@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>

Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Woodcock, Janet

<Janet.Woodcock@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

Subject: RE: materials for 3/18 Internal Confidential Deliberative

Looping in Janet and Patrizia, as this issue came up on the call Anand and I had with them yesterday.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov



From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 8:42 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: materials for 3/18 Internal Confidential Deliberative

Hi – with respect the:

(b)(5)

(b)(5)

(b)(5)

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 17, 2020 10:39 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: materials for 3/18 Internal Confidential Deliberative

Good Evening, attached are materials for tomorrow. I have listed EUAs below and we can updated with the latest numbers tomorrow morning. Thanks all.

Talking Points and Backgrounders (reminder items in red are CCI)

<< File: 2020.03.18 WHTF.docx >>

Therapeutics Talking Points

<< File: v4 2020.03.17 Draft Therapeutics Talking Points with Chloroquine.docx >>

(b)(5)

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/18/2020 1:27:36 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
Subject: New EO on medical product prioritization/allocation

Just a quick heads up the NSC just noted they'll be circulating a new EO today for quick review ("Prioritizing and Allocating Medical Products for the Response to COVID-19"). The President just mentioned it during a press briefing, and apparently it's one of the pre-scripted EOs that OGCs clear every 2 years. I'll forward it if I receive it from the NSC, but wanted to give you a heads up if you were to receive it from other channels. There will be a very tight timeline for review.

In addition, given the medical product (and food service, researcher, etc.) movement issues due to curfews in certain states and jurisdictions, [REDACTED] (b)(5)

[REDACTED] (b)(5)

[REDACTED] (b)(5)

Thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) / [REDACTED] (b)(6) [REDACTED] (cell)
brooke.courtney@fda.hhs.gov

From: O'Shaughnessy, Jacqueline A [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3FCC0BBFC81941E497313B309196F28B-OSHAUGHNESS]
Sent: 3/18/2020 2:41:27 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Convert to PDF asap please
Attachments: Chloroquine-OCS_Letterhead.docx; Chloroquine-OCS_Letterhead.pdf

From: Hinton, Denise <Denise.Hinton[REDACTED]>
Sent: Wednesday, March 18, 2020 2:40 PM
To: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy[REDACTED]>
Subject: Convert to PDF asap please

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/18/2020 4:02:58 PM
To: Margerrison, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12386cee44f645b69f7215d42b265d70-Edward.Marg]
Subject: Question re potential submission: Summary re: Laser Inactivation of Viruses
Attachments: Vaccines for Corona Virus Summary.pdf

Good afternoon Ed,

Please find attached a summary of Dr. Achilefu's proposed technology for laser inactivation of viruses. Feel reach out to him at the number or email listed below for further information. I can provide you some back ground if you'd like to touch base.

Samuel Achilefu, PhD, FRSC
Optical Radiology Lab, MIR, WUSM
4515 McKinley Ave, St. Louis, MO 63110

(b)(6)

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Best,
Denise

(b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/18/2020 4:03:51 PM
To: Johanson, Elaine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]
Subject: FYSA: Summary re: Laser Inactivation of Viruses
Attachments: Vaccines for Corona Virus Summary.pdf

Potential?

Please find attached a summary of Dr. Achilefu's proposed technology for laser inactivation of viruses. Feel reach out to him at the number or email listed below for further information.

Samuel Achilefu, PhD, FRSC
Optical Radiology Lab, MIR, WUSM
4515 McKinley Ave, St. Louis, MO 63110

(b)(6)

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.

Best,
Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/18/2020 4:05:12 PM
To: Cho, David S (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d47af9d991af4c1fbf7cb4c1d287f83e-ChoD]
Subject: Question re potential submission: Summary re: Laser Inactivation of Viruses
Attachments: Vaccines for Corona Virus Summary.pdf

Hi David,

Please find attached a summary of Dr. Achilefu's proposed technology for laser inactivation of viruses. Feel reach out to him at the number or email listed below for further information. I'm available at any time if you'd like additional background.

Samuel Achilefu, PhD, FRSC
Optical Radiology Lab, MIR, WUSM
4515 McKinley Ave, St. Louis, MO 63110

(b)(6)

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.

Best,

Denise (b)(6)

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/18/2020 4:41:22 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc756008a41407282a58324a7b5144a-OCCRequests]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: New EO: PRIORITIZING AND ALLOCATING HEALTH AND MEDICAL RESOURCES TO RESPOND TO THE SPREAD OF COVID-19
Attachments: SOC for ISCM_03.18.2020.pdf; 2020COVID-19DPASupplyChain.eo.docx

In follow up to below on the new EO, here is the ask:

(b)(5)

(b)(5) [see signed version] (Action: ALL, by 03/19/2020 @ 1:00 P.M.)

How would you like to coordinate the FDA review?

Thanks,
Brooke

From: Courtney, Brooke
Sent: Wednesday, March 18, 2020 4:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: EO: PRIORITIZING AND ALLOCATING HEALTH AND MEDICAL RESOURCES TO RESPOND TO THE SPREAD OF COVID-19

(b)(5)

From: Jonas, Seth H. EOP/NSC; (b)(6)
Sent: Wednesday, March 18, 2020 4:26 PM
To: thomas.mcdermott@hq.dhs.gov; Samuel.kaplan@hq.dhs.gov; robert.kolasky@cisa.dhs.gov; robert.elenn@fema.dhs.gov; Glabe, Scott <scott.glabe@hq.dhs.gov>; Friedman, Scott <Scott.Friedman@cisa.dhs.gov>; john.p.polowczyk.mil@mail.mil; kristina.m.obrien2.civ@mail.mil; sean.plankey@hq.doe.gov; Edens, Mandy - OSHA <Edens.Mandy@dol.gov>; Marcia.bernicat@state.gov; jonathan.margolis@state.gov; GlasserJL@state.gov; donna.o'berry@dot.gov; S60.Policy@dot.gov; wiley.deck@dot.gov; Nazak.Nikakhtar@trade.gov; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Courtney, Brooke <Brooke.Courtnev@fda.hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Lailee.Moghtader@treasury.gov; michelle.colby@usda.gov; Hughes, William C. (ODAG <William.C.Hughes@usdoj.gov>; Stanich, Ted <Stanich.Ted@epa.gov>; Lin, Merry S. EOP/WHO <Merry.S.Lin@who.eop.gov>; 'david.short@dot.gov'; Kalutkiewicz, Katherine R. EOP/WHO <Katherine.R.Kalutkiewicz@who.eop.gov>; MaryDee.Beal@usda.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; sam.kaplan@hq.dhs.gov
Cc: DL NSC Supply Chain <DL.NSC.SupplyChain@nsc.eop.gov>; Abbott, Christopher J. EOP/WHO

(b)(6) Crozer, William F. EOP/WHO (b)(6); Baehr, James S.
EOP/WHO (b)(6); Boles, Cassie L. EOP/OMB (b)(6) Farquharson,
Christine E. EOP/OMB (b)(6) Garufi, Marc A. EOP/OMB
(b)(6) McCormack, Brian V. EOP/OMB (b)(6) Lang, Jon D.
EOP/NSC (b)(6) Sinclair, Michael R. EOP/NSC (b)(6) Davis, May
M. EOP/WHO (b)(6) Chafin, Kelly B. EOP/NSC (b)(6) Ferro, Phil J.
EOP/NSC (b)(6) Fabina, Lauren C. EOP/NSC (b)(6) Lowry, Patrick J.
EOP/NSC (b)(6) Merkel, Theo W. EOP/WHO (b)(6) Russo,
Joseph H. EOP/WHO (b)(6)

Subject: RE: Interagency Supply Chain Meeting for Wednesday March 18, 1:00pm-2:00pm

All EO has been signed and is now attached.

From: Jonas, Seth H. EOP/NSC

Sent: Wednesday, March 18, 2020 2:54 PM

To: (b)(6) (b)(6)
(b)(6)
'robert.glenn@fema.dhs.gov' (b)(6) 'Glabe, Scott' (b)(6) 'Friedman, Scott'
(b)(6) (b)(6)
(b)(6) dens, Mandy - OSHA (b)(6)

(b)(6)

<Brooke.Courtney@fda.hhs.gov>; 'bop1@cdc.gov' <bop1@cdc.gov>; 'Marston, Hilary (NIH/NIAID) [E'
<hilary.marston@nih.gov> (b)(6)
'michelle.colby@usda.gov': <michelle.colby@usda.gov>; 'Hughes, William C. (ODAG)' <William.C.Hughes@usdoj.gov>:
(b)(6)

Kalutkiewicz, Katherine R. EOP/WHO (b)(6) 'MaryDee.Beal@usda.gov'
<MaryDee.Beal@usda.gov>

Cc: DL NSC Supply Chain (b)(6) Abbott, Christopher J. EOP/WHO
(b)(6) Crozer, William F. EOP/WHO (b)(6); Baehr, James S.
EOP/WHO (b)(6); Boles, Cassie L. EOP/OMB (b)(6) Farquharson,
Christine E. EOP/OMB (b)(6) Garufi, Marc A. EOP/OMB
(b)(6) McCormack, Brian V. EOP/OMB (b)(6) Lang, Jon D.
EOP/NSC (b)(6) Sinclair, Michael R. EOP/NSC (b)(6) Davis, May
M. EOP/WHO (b)(6) Chafin, Kelly B. EOP/NSC (b)(6) Ferro, Phil J.
EOP/NSC (b)(6) Fabina, Lauren C. EOP/NSC (b)(6) Lowry, Patrick J.
EOP/NSC (b)(6); Merkel, Theo W. EOP/WHO (b)(6) Russo,
Joseph H. EOP/WHO (b)(6)

Subject: RE: Interagency Supply Chain Meeting for Wednesday March 18, 1:00pm-2:00pm

Dear Interagency Supply Chain Group Members,

Please see the SOC and draft docs attached for your consideration.

From: Jonas, Seth H. EOP/NSC

Sent: Tuesday, March 17, 2020 9:03 PM

To: (b)(6)
(b)(6)
(b)(6) 'Glabe, Scott' (b)(6) 'Friedman, Scott'

(b)(6)
(b)(6)
(b)(6) Edens, Mandy - OSHA (b)(6)
(b)(6)
(b)(6) Brooke.Courtney@fda.hhs.gov'
<Brooke.Courtney@fda.hhs.gov>; 'bop1@cdc.gov' <bop1@cdc.gov>; 'Marston, Hilary (NIH/NIAD) [E'
<hilary.marston@nih.gov>; (b)(6)
'michelle.colby@usda.gov' <michelle.colby@usda.gov>; 'Hughes, William C. (ODAG' <William.C.Hughes@usdoj.gov>;
'Stanich, Ted' (b)(6) Lin, Merry S. EOP/WHO (b)(6)
Cc: DL NSC Supply Chain (b)(6) Abbott, Christopher J. EOP/WHO
(b)(6) Crozer, William F. EOP/WHO (b)(6); Baehr, James S.
EOP/WHO (b)(6) Boles, Cassie L. EOP/OMB (b)(6) Farquharson,
Christine E. EOP/OMB (b)(6) Garufi, Marc A. EOP/OMB
(b)(6) McCormack, Brian V. EOP/OMB (b)(6) Lang, Jon D.
EOP/NSC (b)(6) Sinclair, Michael R. EOP/NSC (b)(6) Davis, May
M. EOP/WHO (b)(6) Chafin, Kelly B. EOP/NSC (b)(6) Ferro, Phil J.
EOP/NSC (b)(6) Fabina, Lauren C. EOP/NSC (b)(6) Lowry, Patrick J.
EOP/NSC (b)(6) Merkel, Theo W. EOP/WHO (b)(6) Russo,
Joseph H. EOP/WHO (b)(6)
Subject: Interagency Supply Chain Meeting for Wednesday March 18, 1:00pm-2:00pm

Sent on behalf of Brian J. Cavanaugh, Senior Director for Resilience Policy and Special Assistant to the President

Good Evening-

Tomorrow, March 18, from 1300-1400, we would appreciate your attendance at an Interagency Supply Chain Meeting co-convened by NSC and NEC.

D/As are encouraged to join by SVTC. Please have your video ops center contact WHSR to ensure connections.

If joining by conference call: Participant dial-in: (202)395-6392 (b)(6)

EOP members may attend in person in EEOB Room (b)(6)

Sent: 3/18/2020 7:38:22 PM
To: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]
Subject: HHS International SPOTREP: COVID-19 / FDA SitRep
Attachments: COVID-19 SLB 18Mar20 Final.pdf

// FOR OFFICIAL USE ONLY

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/18/2020 9:38:14 PM
To: Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]
Subject: CLOSE HOLD FYSA: Dear Governor.docx
Attachments: Dear Governor.docx

FYI – from today’s SITREP (Red is CCI info)

– **Sample Collection Swabs and Alternatives:**

- CDRH has been facilitating the short-term distribution of the nasopharyngeal (NP) swabs here in the US. A military transport is flying swabs from (b)(4) to the US to aid with transportation issues. The 1st shipment arrived this morning in Memphis TN to distribute nationally with the aid of (b)(4) non-public information).

(b)(4)

- The FAQ will be updated to include mid turbinate and oropharyngeal (OP) sampling is acceptable, although nasopharyngeal is preferred. This would allow the use of a more standard, shorter swab for sample collection.
- CDRH is also in touch with a domestic supplier of swabs and media that may be able to provide more of their product to domestic customers.

From: Hinton, Denise
Sent: Wednesday, March 18, 2020 9:36 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: CLOSE HOLD FYSA: Dear Governor.docx

Thanks for info – OCET is working with OPLIA on the following draft document.

Best,
Denise

To: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]

Subject: COVID19 Updates

Attachments: 19Mar20 - 0815ET HHS COVID-19 Operational Update Brief.pdf; 39_2019-nCoV Outbreak_FDA SITREP_18 March 2020.docx

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 10:32:15 AM
To: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]
Subject: COVID19 Updates
Attachments: 19Mar20 - 0815ET HHS COVID-19 Operational Update Brief.pdf; 39_2019-nCoV Outbreak_FDA SITREP_18 March 2020.docx

Good morning Bill and Tucker,

Attached for your situational awareness is the 18 March FDA 2019-nCoV SITREP.

Please do not share outside of FDA and consider restricting further internal distribution to those involved in the response as much of this information is very sensitive, close hold, internal as identified in the attached document.

Thank you,

Denise & Michael

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 6:45:11 PM
To: Nabakowski, Andrei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c8bcecc310c4e45a5012d47d40886e1-NABAKOWSKIA]
Subject: FW: FOR YOUR REVIEW: today's all hands
Attachments: Day 4 all hands.rtf

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Thursday, March 19, 2020 4:59 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Cc: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>
Subject: FOR YOUR REVIEW: today's all hands

Please review today's draft all hands. OO secured clearance with center EOs on the 3rd paragraph detailing reporting requirements.

(b)(5)

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 7:30:30 PM
To: Nwaba, Nina C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b2ad06c49754947b02fec16395bad21-NMN]
Subject: RE: N-95 Mask EUA Request

(b)(5)

Hope you are well!

From: Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>
Sent: Thursday, March 19, 2020 7:02 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>
Subject: FW: N-95 Mask EUA Request

Greetings RADM Hinton,

I hope this find you well and thank you for all your work on COVID-19. I forwarded Dr. Al's email to COVID taskforce and the office that handles PPE. Please see email below.

Thanks,

Nina

*Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Deputy Director (Acting)*

OHT5: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm 4114 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-5494
Nina.Nwaba@fda.hhs.gov



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From: Al Romanosky -MDH- <al.romanosky@maryland.gov>
Sent: Thursday, March 19, 2020 4:06 PM

To: Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; CDRH-EUA-Templates <(b)(6)>
Subject: RE: N-95 Mask EUA Request

Nina,
Thank you,
Regards,
Dr Al



Albert J Romanosky MD PhD

Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Dept of Health
300 West Preston Street, Rm 202
Baltimore, MD 21201

Al.Romanosky@Maryland.Gov

Phone: 410.767.0823

Mobile: (b)(6)

Fax: 410.333.5000

24/7 Emergency Pager: (b)(6)

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From: Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>
Sent: Thursday, March 19, 2020 3:49 PM
To: CDRH-EUA-Templates <(b)(6)>
Cc: Al Romanosky -MDH- <al.romanosky@maryland.gov>
Subject: FW: N-95 Mask EUA Request

FYI

*Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT., United States Public Health Service
Deputy Director (Acting)*

OHT5: Office of Neurological and Physical Medicine Devices
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From: Al Romanosky -MDH- <al.romanosky@maryland.gov>

Sent: Thursday, March 19, 2020 3:33 PM

To: CDRH-NonDiagnosticEUA-Templates <(b)(6)>; CVSDBadmin@cdc.gov; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Bonzagni, Neil <Neil.Bonzagni@fda.hhs.gov>; Echeozo, Kodilichi <Kodilichi.Echeozo@fda.hhs.gov>; Lee, Joy <Joy.Lee@fda.hhs.gov>; L. Shenee' Toombs <(b)(6)>; Liberatore, Mark <Mark.Liberatore@fda.hhs.gov>; Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; Chen, Peter <Peter.Chen@fda.hhs.gov>; Al Romanosky -MDH- <al.romanosky@maryland.gov>; Christopher Snyder -MDH- <csnyder@maryland.gov>; Nicole Brown <Nicole.Brown@maryland.gov>; Sara Barra -MDH- <sara.barra@maryland.gov>; Sherry Adams -MDH- <sherry.adams@maryland.gov>; Tracy Bryan -MDH- <tracy.bryan@maryland.gov>; Veronica Black -MDH- <veronica.black@maryland.gov>

Subject: N-95 Mask EUA Request

Good afternoon,

The Office of Preparedness and Response is submitting a request to have the Kimberly Clark 46727 and 46728 N-95 respirators added to Appendix B under the recent FDA Coronavirus Emergency Use Authorization for PPE. (See below and attached)

I apologize for sending this to my FDA colleagues but I was unsure how to make sure that this request reaches the FDA offices and divisions required to consult and concur with this request. As always thank you for your time, assistance and dedication in service to the residents of the US.

Warmest regards,

Dr Al

3/16/2020

Albert J Romanosky MD PhD

Medical Director / State Emergency Preparedness Coordinator

Office of Preparedness and Response, Maryland Department of Health

300 West Preston St, Rm 202

Baltimore, MD 21201

RADM Denise M. Hinton

Chief Scientist Food and Drug Administration

25 New Hampshire Ave,

Silver Spring, MD 20903

Re: Request for Consultation and Concurrence

Coronavirus Emergency Use Authorization

Dated 2 March 2020

Dear RADM Hinton,

The Maryland Department of Health (MDH), Office of Preparedness and Response (OP&R) is submitting an Emergency Use Authorization (EUA) request to add Kimberly Clark filtering facepiece respirators (FFRs) to *Appendix B: Authorized Respirators* as described in the Scope of Authorization Section of the Letter of Authorization (Section II) and pursuant to the Conditions of Authorization in the recent FDA Coronavirus EUA declaration dated 2 March 2020.

As a Strategic Stockpiler of medical supplies, equipment and medications in support of Maryland's public health and medical stakeholders and partners during disaster and emergency response operations, OP&R is entitled to make this request under Section 2 of the Coronavirus EUA.

OP&R requests consultation with both CDC Chronic Viral Diseases Branch (CVDB) and FDA (Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH), Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

In addition, upon concurrence following this consultation, OP&R requests that Kimberly Clark respirators (N95, Disposable Healthcare Respirator, Flat-Fold, Universal, Models KC46727 (regular size) / KC46827 (Small)) currently listed in OP&R inventory and listed in *Appendix A – NIOSH Approved FFRs as of 02-29-20* be added to *Appendix B: Authorized Respirators* in the FDA Coronavirus EUA

(b)(5)

However, as a result of increased demand and utilization and restricted supply chain availability, a critical shortage of approved FFRs has occurred during the current coronavirus public health emergency. There are not enough quantities of respiratory protective devices available that comply with FDA's regulatory authority to meet the needs of the United States healthcare system.

This shortage places healthcare providers a great risk of exposure and illness related to SARS CoV2 infection.

Thus, OP&R petitions for approval of the current on-hand inventory of Kimberly Clark respirators and subsequent use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the Coronavirus Disease 2019 (COVID-19)³ outbreak.

The following established facts support OP&R's request:

- SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
- On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens as a result of COVID-19.
- Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.
- Based on the totality of scientific evidence available to FDA:
 - it is reasonable to believe that authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages;
 - that known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages, outweigh the known and potential risks of such product;

- There is no adequate, approved, and available alternative to the emergency use of the respirators described for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.
- Presidential Emergency Declaration regarding the Coronavirus Public Health Emergency on 13 March 2020.

Office of Preparedness and Response Data Analysis and Justification for EUA Request

The Maryland Department of Health, Environmental Health Bureau Medical Director, Dr Cliff Mitchell and the OP&R Medical Director and State Emergency Preparedness Coordinator, Dr Al Romanosky, conducted a review and analysis of ten NIOSH reports detailing the performance results of respirators sampled from ten stockpile facilities.

The NIOSH reports presented testing results following reassessment of 3M, Moldex and Kimberly Clark respirators in long term storage at the stockpile facilities. Drs Mitchell and Romanosky focused on testing results for KC 46727 and KC 76827 N-95 respirators.

Eight of ten warehouse had Kimberly Clark respirators in their inventory. Respirators from a total of 28 samples were tested for a total of 926 respirators (average of 33 respirators collected for each sample tested).

(b)(5)

NIOSH Testing Of N-95 Face Masks

NIOSH visited ten warehouse locations where PPE is stored as part of the SNS program. Random samples of various N-95 masks were collected from various lots of face masks.

NIOSH Standard Test Procedures with Pass / Fail Criteria:

- Inhalation resistance: pass <35 mm H2O column @ 85 LPM
- exhalation resistance: pass <25 mm H2O column @ 85 liters per minute (LPM)
- Filtration: <5.0% particulate penetration
- Efficiency for N95: (>95.0% filter efficiency)

Visual Inspection of Containers and Face Masks:

- no dust or damage to product packaging
- damage to respirator no visible water / chemical exposure

Storage Conditions with Documented %Relative Humidity and Temperature

- Temperature / humidity controlled
- Limited sun light / light exposure

(b)(5)

OP&R conducted a review of the 10 NIOSH Reports pertaining to the assessment of N-95 Masks following long term storage.

Findings of NIOSH Reassessment for Kimberly Clark N-95 Respirators

Number of warehouses containing Kimberly Clark Respirators:

8/10 Warehouses had an inventory of Kimberly Clark masks

(b)(5)

Kimberly Clark N-95 Respirators found in the repository samples

KC 46727 (regular size) / KC 46827 (small size)

Total Sample Lots of Kimberly Clark Respirators Tested

28 sample lots selected during sampling (926 total masks tested)

NIOSH N-95 Standard Test Procedure Results for Kimberly Clark Masks

Inhalation Pressure Test: **100% passed (28/28)**

Exhalation Pressure Test: **100% passed (28/28)**

Percent Particulate Penetration Testing / Filtration

26/28 passed: 95% of particles 03 microns were filtered (pass: 5.0);

Test target value: Filter 95% of 0.3-micron size particles.

NOTE: CoVid 19 particle size (0.13 microns)

Particle penetration failures: 2/28 lots (33 of 926 Failure: 7% failure rate)

Failure scores:

5.5 (interpretation that this tested group from a single warehouse had a percent filtration rate of 94.5% (target 95%); **3.5% failure rate**

8.0 for a sampling for a single warehouse for a percent filtration percentage of 92%; **(b)(5)**

(b)(5)

Interpretation of The Findings

Following detailed review of the ten NIOSH reports on N-95 face masks selected from ten warehouses, a100% of the Kimberly Clark N-95 face masks passed both the inspiratory and exhalation pressure Standard Test Procedures.

(b)(5)

(b)(5)

(b)(5)

Summary Finding

Based on totality of scientific evidence, it is reasonable belief that the Kimberly Clark respirators: will be effective and represent a critical emergency supply critical to Maryland's response to this public health emergency.

Therefore, it is reasonable to believe that the known and potential benefits of permitting use of the OP&R inventory of Kimberly Clark respirators (800,000+), when used consistently with the Scope of Authorization of the Coronavirus EUA (Section II), outweigh the known and potential risks of such a product.

Terms Following Approval of OP&R Coronavirus EUA Request

Upon approval of our request, OP&R will adhere to the following requirements as delineated in the Coronavirus EUA, IV Conditions of Authorization.

Respirator Labeling

- Authorized Kimberly Clark respirators will be labeled:
 - approved by NIOSH

(b)(5)

Adverse Events Reporting

- To the extent feasible given the emergency circumstances, the Office of Preparedness and Response will maintain reports of adverse events received from healthcare personnel and facilities to which the authorized respirators are distributed.
 - Adverse events of which OP&R becomes aware will be reported to FDA via Medwatch Forms for FDA Safety Reporting.

Additional EUA Requests

(b)(5)

- OP&R will submit a request to FDA with a copy of the request to CDC (CVSDBadmin@cdc.gov) and specifying the manufacturer, model number, and the product expiry date.
- Such requests will be made by OP&R in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

EUA Record Keeping and Inspection

- OP&R will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request

EUA Termination

- OP&R utilization of the Kimberly Clark respirators will be effective until:
 - the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

- o Existing inventory is depleted.

Thank you in advance for your time and consideration of this request.

Sincerely yours



Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Department of Health

- CC:
- CDC Chronic Viral Diseases Branch Admin
 - FDA: Office of Strategic Partnerships and Technology Innovation (OST)
 - FDA: Center for Devices and Radiological Health (CDRH)
 - FDA: Division of Infection Control and Plastic and Reconstructive Surgery/CDRH
 - FDA: Office of Counterterrorism and Emerging Threats (OCET)
 - FDA: Office of the Chief Scientist (OCS)
 - FDA: Office of the Commissioner (OC).



Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Dept of Health
300 West Preston Street, Rm 202
Baltimore, MD 21201
Al.Romanosky@Maryland.Gov
Phone: 410.767.0823
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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 7:50:50 PM
To: Al Romanosky -MDH- [al.romanosky@maryland.gov]
CC: CDRH-NonDiagnosticEUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b31298151e33457eae63d331b684e15c-CDRH-NonDia]; CVSDBadmin@cdc.gov; Bonzagni, Neil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=68c5a96cf0d8459ea7e716faa384908a-Neil.Bonzag]; Echeozo, Kodilichi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c2122c5657d4f5f972e4007e91095cf-Kodilichi.N]; Lee, Joy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b961a515b1654bf6a9f99c0a4cbab40e-Joy.Lee]; L. Shenee' Toombs [sheneet@hotmail.com]; Liberatore, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=27348f6641034ef38c936a509c076e66-LIBERATOREM]; Nwaba, Nina C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b2ad06c49754947b02fec16395bad21-NMN]; Chen, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e0645b3f6b604a77b713bb2a16f79d84-CHENP]; Christopher Snyder -MDH- [csnyder@maryland.gov]; Nicole Brown [Nicole.Brown@maryland.gov]; Sara Barra -MDH- [sara.barra@maryland.gov]; Sherry Adams -MDH- [sherry.adams@maryland.gov]; Tracy Bryan -MDH- [tracy.bryan@maryland.gov]; Veronica Black -MDH- [veronica.black@maryland.gov]; CDRH-EUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf0733393d74e80a407946c10c53411-CDRH-EUA-Te]
Subject: RE: N-95 Mask EUA Request

Thank you, Dr. Al.

(b)(5)

Best,

Denise

From: Al Romanosky -MDH- <al.romanosky@maryland.gov>
Sent: Thursday, March 19, 2020 7:37 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: CDRH-NonDiagnosticEUA-Templates <CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov>; CVSDBadmin@cdc.gov; Bonzagni, Neil <Neil.Bonzagni@fda.hhs.gov>; Echeozo, Kodilichi <Kodilichi.Echeozo@fda.hhs.gov>; Lee, Joy <Joy.Lee@fda.hhs.gov>; L. Shenee' Toombs <(b)(6)>; Liberatore, Mark <Mark.Liberatore@fda.hhs.gov>; Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; Chen, Peter <Peter.Chen@fda.hhs.gov>; Christopher Snyder -MDH- <csnyder@maryland.gov>; Nicole Brown <Nicole.Brown@maryland.gov>; Sara Barra -MDH- <sara.barra@maryland.gov>; Sherry Adams -MDH- <sherry.adams@maryland.gov>; Tracy Bryan -MDH- <tracy.bryan@maryland.gov>; Veronica Black -MDH- <veronica.black@maryland.gov>
Subject: Re: N-95 Mask EUA Request

Denise,
good evening,

thank you for the email. I hope everything is going well, all things considered.

(b)(5)

(b)(5)

Please let me know if there is anything I can do to support FDA given that you are primarily located in Maryland.

Warmest regards,
Dr Al

Albert J Romanosky MD PhD

Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Dept of Health
300 West Preston Street, Rm 202
Baltimore, MD 21201

Al.Romanosky@Maryland.Gov

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On Thu, Mar 19, 2020 at 6:58 PM Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Dear Dr. Al,

(b)(5)

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

From: Al Romanosky -MDH- <al.romanosky@maryland.gov>

Sent: Thursday, March 19, 2020 3:33 PM

To: CDRH-NonDiagnosticEUA-Templates <CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov>; CVSDBadmin@cdc.gov; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Bonzagni, Neil <Neil.Bonzagni@fda.hhs.gov>; Echeozo, Kodilichi <Kodilichi.Echeozo@fda.hhs.gov>; Lee, Joy <Joy.Lee@fda.hhs.gov>; L. Shenee' Toombs <(b)(6)>; Liberatore, Mark

<Mark.Liberatore@fda.hhs.gov>; Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; Chen, Peter <Peter.Chen@fda.hhs.gov>; Al Romanosky -MDH- <al.romanosky@maryland.gov>; Christopher Snyder -MDH- <csnyder@maryland.gov>; Nicole Brown <Nicole.Brown@maryland.gov>; Sara Barra -MDH- <sara.barra@maryland.gov>; Sherry Adams -MDH- <sherry.adams@maryland.gov>; Tracy Bryan -MDH- <tracy.bryan@maryland.gov>; Veronica Black -MDH- <veronica.black@maryland.gov>

Subject: N-95 Mask EUA Request

Good afternoon,

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Warmest regards,

Dr Al

3/16/2020

Albert J Romanosky MD PhD

Medical Director / State Emergency Preparedness Coordinator

Office of Preparedness and Response, Maryland Department of Health

300 West Preston St, Rm 202

Baltimore, MD 21201

RADM Denise M. Hinton

Chief Scientist Food and Drug Administration

25 New Hampshire Ave,

Silver Spring, MD 20903

Re: Request for Consultation and Concurrence

Coronavirus Emergency Use Authorization

Dated 2 March 2020

Dear RADM Hinton,

The Maryland Department of Health (MDH), Office of Preparedness and Response (OP&R) is submitting an Emergency Use Authorization (EUA) request to add Kimberly Clark filtering facepiece respirators (FFRs) to *Appendix B: Authorized Respirators* as described in the Scope of Authorization Section of the Letter of Authorization (Section II) and pursuant to the Conditions of Authorization in the recent FDA Coronavirus EUA declaration dated 2 March 2020.

As a Strategic Stockpiler of medical supplies, equipment and medications in support of Maryland's public health and medical stakeholders and partners during disaster and emergency response operations, OP&R is entitled to make this request under Section 2 of the Coronavirus EUA.

OP&R requests consultation with both CDC Chronic Viral Diseases Branch (CVDB) and FDA (Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH), Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

In addition, upon concurrence following this consultation, OP&R requests that Kimberly Clark respirators (N95, Disposable Healthcare Respirator, Flat-Fold, Universal, Models KC46727 (regular size) / KC46827 (Small)) currently listed in OP&R inventory and listed in *Appendix A – NIOSH Approved FFRs as of 02-29-20* be added to *Appendix B: Authorized Respirators* in the FDA Coronavirus EUA

These Kimberly Clark respirators are approved by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR Part 84, as non-powered air purifying particulate FFRs. Although approved, they have since passed the manufacturers' recommended shelf-life, for use in healthcare settings by healthcare personnel (HCP).

However, as a result of increased demand and utilization and restricted supply chain availability, a critical shortage of approved FFRs has occurred during the current coronavirus public health emergency. There are not enough quantities of respiratory protective devices available that comply with FDA's regulatory authority to meet the needs of the United States healthcare system.

This shortage places healthcare providers a great risk of exposure and illness related to SARS CoV2 infection.

Thus, OP&R petitions for approval of the current on-hand inventory of Kimberly Clark respirators and subsequent use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the Coronavirus Disease 2019 (COVID-19)³ outbreak.

The following established facts support OP&R's request:

- SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
- On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens as a result of COVID-19.
- Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.
- Based on the totality of scientific evidence available to FDA:
 - it is reasonable to believe that authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages;
 - that known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages, outweigh the known and potential risks of such product;
 - There is no adequate, approved, and available alternative to the emergency use of the respirators described for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.
- Presidential Emergency Declaration regarding the Coronavirus Public Health Emergency on 13 March 2020.

Office of Preparedness and Response Data Analysis and Justification for EUA Request

The Maryland Department of Health, Environmental Health Bureau Medical Director, Dr Cliff Mitchell and the OP&R Medical Director and State Emergency Preparedness Coordinator, Dr Al Romanosky, conducted a review and analysis of ten NIOSH reports detailing the performance results of respirators sampled from ten stockpile facilities.

The NIOSH reports presented testing results following reassessment of 3M, Moldex and Kimberly Clark respirators in long term storage at the stockpile facilities. Drs Mitchell and Romanosky focused on testing results for KC 46727 and KC 76827 N-95 respirators.

Eight of ten warehouse had Kimberly Clark respirators in their inventory. Respirators from a total of 28 samples were tested for a total of 926 respirators (average of 33 respirators collected for each sample tested).

In a letter dated 7 June 2018, Kimberly Clark “*recommended* disposing of any product that is beyond the established shelf life, has not been stored according to the user instructions, is damaged, does not provide a proper fit, or has missing parts”.

NIOSH Testing Of N-95 Face Masks

NIOSH visited ten warehouse locations where PPE is stored as part of the SNS program. Random samples of various N-95 masks were collected from various lots of face masks.

NIOSH Standard Test Procedures with Pass / Fail Criteria:

- Inhalation resistance: pass <35 mm H2O column @ 85 LPM
- exhalation resistance: pass <25 mm H2O column @ 85 liters per minute (LPM)
- Filtration: <5.0% particulate penetration
- Efficiency for N95: (>95.0% filter efficiency)

Visual Inspection of Containers and Face Masks:

- no dust or damage to product packaging
- damage to respirator no visible water / chemical exposure

Storage Conditions with Documented %Relative Humidity and Temperature

- Temperature / humidity controlled
- Limited sun light / light exposure

Based upon the findings of the NIOSH evaluation as well as the letter from Kimberly Clark, the recommendations concerning utilization of the Kimberly Clark N-95 face masks was

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OP&R conducted a review of the 10 NIOSH Reports pertaining to the assessment of N-95 Masks following long term storage.

Findings of NIOSH Reassessment for Kimberly Clark N-95 Respirators

Number of warehouses containing Kimberly Clark Respirators:

8/10 Warehouses had an inventory of Kimberly Clark masks

Range of Long-Term Storage for the N-95 masks

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Kimberly Clark N-95 Respirators found in the repository samples

KC 46727 (regular size) / KC 46827 (small size)

Total Sample Lots of Kimberly Clark Respirators Tested

28 sample lots selected during sampling (926 total masks tested)

NIOSH N-95 Standard Test Procedure Results for Kimberly Clark Masks

Inhalation Pressure Test: **100% passed (28/28)**

Exhalation Pressure Test: **100% passed (28/28)**

Percent Particulate Penetration Testing / Filtration

26/28 passed: 95% of particles 03 microns were filtered (pass: 5.0);

Test target value: Filter 95% of 0.3-micron size particles.

NOTE: CoVid 19 particle size (0.13 microns)

Particle penetration failures: 2/28 lots (33 of 926 Failure: 7% failure rate)

Failure scores:

5.5 (interpretation that this tested group from a single warehouse had a percent filtration rate of 94.5% (target 95%); **3.5% failure rate**

8.0 for a sampling for a single warehouse for a percent filtration percentage of 92%; **3.5% failure rate**

Although, the Kimberly Clark masks failed at two individual warehouses, the other warehouses most likely contained masks produced during the sample product5oin period, Therefore, these findings may represent aberrancies and not reflect the whole of the Kimberly Clark N-95 face Masks.

Interpretation of The Findings

Following detailed review of the ten NIOSH reports on N-95 face masks selected from ten warehouses, a100% of the Kimberly Clark N-95 face masks passed both the inspiratory and exhalation pressure Standard Test Procedures.

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Therefore, based upon the review of the NIOSH re-assessments and the performance of the Kimberly Clark Masks, I feel that they could be used as N-95 respirators in lieu of current masks which are in extremely short supply.

Summary Finding

Based on totality of scientific evidence, it is reasonable belief that the Kimberly Clark respirators: will be effective and represent a critical emergency supply critical to Maryland’s response to this public health emergency.

Therefore, it is reasonable to believe that the known and potential benefits of permitting use of the OP&R inventory of Kimberly Clark respirators (800,000+), when used consistently with the Scope of Authorization of the Coronavirus EUA (Section II), outweigh the known and potential risks of such a product.

Terms Following Approval of OP&R Coronavirus EUA Request

Upon approval of our request, OP&R will adhere to the following requirements as delineated in the Coronavirus EUA, IV Conditions of Authorization.

Respirator Labeling

- Authorized Kimberly Clark respirators will be labeled:
 - approved by NIOSH

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Adverse Events Reporting

- To the extent feasible given the emergency circumstances, the Office of Preparedness and Response will maintain reports of adverse events received from healthcare personnel and facilities to which the authorized respirators are distributed.
 - Adverse events of which OP&R becomes aware will be reported to FDA via Medwatch Forms for FDA Safety Reporting.

Additional EUA Requests

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- OP&R will submit a request to FDA with a copy of the request to CDC (CVSDBadmin@cdc.gov) and specifying the manufacturer, model number, and the product expiry date.
- Such requests will be made by OP&R in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

EUA Record Keeping and Inspection

- OP&R will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request

EUA Termination

- OP&R utilization of the Kimberly Clark respirators will be effective until:
 - the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.
 - Existing inventory is depleted.

Thank you in advance for your time and consideration of this request.

Sincerely yours

Albert J Romanosky MD PhD

Albert J Romanosky MD PhD

Medical Director / State Emergency Preparedness Coordinator

Office of Preparedness and Response

Maryland Department of Health

CC:

CDC Chronic Viral Diseases Branch Admin

FDA: Office of Strategic Partnerships and Technology Innovation (OST)

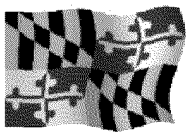
FDA: Center for Devices and Radiological Health (CDRH)

FDA: Division of Infection Control and Plastic and Reconstructive Surgery/CDRH

FDA: Office of Counterterrorism and Emerging Threats (OCET)

FDA: Office of the Chief Scientist (OCS)

FDA: Office of the Commissioner (OC).



Albert J Romanosky MD PhD

Medical Director / State Emergency Preparedness Coordinator

Office of Preparedness and Response

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 7:54:53 PM
To: Slikker, William [William.Slikker@fda.hhs.gov]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]
Subject: FYSA: FDA 2019-nCOV SITREP - 19 March 2020
Attachments: 40_2019-nCoV Outbreak_FDA SITREP_19 March 2020.docx; COVID-19 SLB 19Mar20 Final.pdf

Hi Bill and Tucker,

Attached for your situational awareness is the 19 March FDA 2019-nCoV SITREP sent by Michael Mair this evening and the daily SOC SitRep.

(b)(5)

Best,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/19/2020 9:00:37 PM
To: Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]
Subject: RE: FYI: COVID-19 Update: 15 Days to Slow the Spread--Day 4

That's a great solution – we'll discuss tomorrow.

Thank you!
Denise

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:59 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: FYI: COVID-19 Update: 15 Days to Slow the Spread--Day 4

I do not advise changing it now. We worked long and hard with the centers and that is the role of occ health. Perhaps occ health can provide a weekly report or summary to him as DASHO. We can discuss tomorrow.

Thanks,
Jim

From: "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:57 PM
To: "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>
Subject: FYI: COVID-19 Update: 15 Days to Slow the Spread--Day 4

From: Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:53 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: COVID-19 Update: 15 Days to Slow the Spread--Day 4

There is nothing mentioned in the message about notification to the DASHO for the agency. How do we fix it?
Pillai

From: A Message from the Commissioner <message@fda.hhs.gov>
Date: March 19, 2020 at 8:42:52 PM EDT
To: FDA-Wide <FDA-Wide@fda.hhs.gov>
Subject: COVID-19 Update: 15 Days to Slow the Spread--Day 4

Dear FDA Team,

The FDA's work was center stage in today's White House Coronavirus Task Force press briefing where I had the privilege to discuss some of the critical work currently underway by FDA professionals in combatting the COVID-19 virus. In particular, our efforts to determine the safety and potential effectiveness of certain antiviral medications to treat patients suffering from this virus was the highlight of today.

This is truly a historic time for the world, and one where the FDA has an incredibly crucial role. While we are working at a record pace, I am mindful of the tremendous responsibility that comes with that. As I shared earlier today at the press conference, I recognize the importance of providing hope—and I have great hope and confidence that we will knock down this virus together, but that will never translate into providing false hope because our decision-making will always be driven by data and science.

The health and safety of the FDA community remain a top priority to the FDA Leadership Team. To ensure we safeguard the health of our entire workforce, employees are encouraged to voluntarily notify their immediate supervisor and/or the FDA's Occupational Health Services at (301) 796-2331 or occupationalhealthservices@fda.hhs.gov as soon as possible if they test positive for COVID-19. Any supervisor contacted by an employee confirming they tested positive for the COVID-19 virus should immediately notify their Center Director and Executive Officer for awareness and necessary action. All personal employee information will be kept confidential. Employees are also encouraged to voluntarily notify their immediate supervisor if they had direct contact with someone outside of work who tested positive for COVID-19 to discuss the use of workplace flexibilities, including telework, if not already in place.

The FDA just issued a nationwide call for blood donations, which have been dramatically reduced due to the implementation of social distancing and the cancellation of blood drives. We can fully support the President's Coronavirus Guidelines for America while helping to maintain our nation's blood supply as blood donation centers already have practices in place to facilitate the safe donation of blood and are using additional social distancing precautions. I strongly urge FDA employees to consider donating by making an appointment with their local blood donor center or the Red Cross. #FDAStrong

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs



From: Malais, Tanya [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
Sent: 3/19/2020 10:59:14 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: 3-19-20 COVID-19 AEG Meeting Notes
Attachments: 3-19-20 COVID-19 AEG Meeting Notes.odt

Good evening,

Attached are my notes from the 3/19/20 AEG meeting.

Tanya E. Malais
Planning Section Chief
2019 Novel Coronavirus (nCoV) IMG
Office: 949-608-2984
Mobile: (b)(6)
Planning Section Email: (b)(6)
24 hour Emergency Number: 1-866-300-4374

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/20/2020 8:30:05 AM
To: Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: FW: 3-19-20 COVID-19 AEG Meeting Notes
Attachments: 3-19-20 COVID-19 AEG Meeting Notes.odt

Good morning – compare your notes to these and see how you did.

Thanks,
Denise

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 3/20/2020 9:29:03 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Preparing to Issue: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health
Attachments: 20200318-PR--Hand Sanitizer Guidance FINAL wmeta.docx

From: Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Sent: Friday, March 20, 2020 9:28 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; OMA-Notifications <OMA-Notifications@fda.hhs.gov>
Cc: OC OEA OMA-Press <OCOEAOMA-Press@fda.hhs.gov>
Subject: Preparing to Issue: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health

OMA is preparing to issue the following Press Release: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health

This should post here within the next 30 minutes.

Thank you,
--Jeremy

Jeremy Kahn
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-796-8671
jeremy.kahn@fda.hhs.gov



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/20/2020 9:33:20 AM
To: Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: RE: 9:30 JIC notes + focus topics

Thanks for sharing!

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Friday, March 20, 2020 8:32 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: 9:30 JIC notes + focus topics

Good morning! 9:30 – 10:30 a.m. **WebEx only.** For first ~30 minutes, we will run down status of current items. 10:00-10:30, will focus on forward look/strategy or the day's focus topic (will change—let me know if you have a focus topic for the group). List below. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

Green = comms live today. Red = comms pending [confidential until issued/publicized]

COMMS PIPELINE– for each item below, chime in on plans for:

- ✓ Press
- ✓ Social
- ✓ Other external comms (e.g., consumer, Voices)
- ✓ Stakeholder
- ✓ Web
- ✓ Internal

• **Medical products cross-cutting**

- March 20 web update – Public Health England study expands to apply technology used for an ongoing MCMi Ebola project to gather important information about COVID-19 infection (PHE press release today noted this FDA funding [+LINK](#))
- Diagnostics
 - March 19 – 2 new EUAs (Diasorin Molecular LLC and GenMark Diagnostics, Inc.) w/tweets
 - March 20 – FDA statement on FDA efforts to warn consumers about companies marketing fake COVID-19 diagnostic tests, including home test kits (joint statement by ORA and CDRH)
 - Date TBD – Hahn/Redfield op-ed on diagnostic testing
- Other devices
 - March 20 - FDA statement: Coronavirus (COVID-19) Update: FDA allows for the use of certain non-invasive medical devices to monitor patients' vital signs remotely, reducing the need for hospital visits and minimizing the risk of exposure to coronavirus
 - New Immediately In Effect Guidance on Remote Patient Monitoring Devices (CDRH)
- Therapeutics
 - OCOMM's Division of Drug Information (DDI) has received 1,067 total COVID-19-related questions/concerns to date. Consumer (348), Industry (476), HCP (194), Other (49)
 - Date TBD – Press statement on patient access to certain drugs with a Risk Evaluation and Mitigation Strategy (REMS) during pandemic
 - Date TBD – Reactive statement in response to NSAIDS and COVID-19
- Vaccines / biologics
 - March 19 - Updated Instructions for Submitting Lot Release Samples and Protocols for CBER-regulated Products During the COVID-19 Pandemic posted to web

- PPE
- March 20 – Letter to healthcare providers on conservation strategies for gloves
- Clinical trial updates
- Date TBD - AE reporting on clinical trials during the pandemic

- **Supply chain / shortage updates cross-cutting**
- ~April 1 - CDER/CBER draft guidance regarding permanent discontinuance or interruption in manufacturing
- CDER
 - March 19 –second hand sanitizers guidance posted: Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), (in addition to March 14 Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency)
- Reactive Q&A on these guidances in progress
 - March 20 - FDA statement: Coronavirus (COVID-19) Update: FDA provides guidance to compounders on production of alcohol-based hand sanitizer to help boost supply, protect public health
 - Date TBD - Consumer Q&A
 - Date TBD – Consumer Update on hand sanitizers (appropriate use, etc.)
- CDRH
 - March 20 - Ventilator supply strategies for HCPs guidance
- Press statement in progress
- Stakeholder emails & outreach to hospitals being developed
- CBER
 - March 19 – updated web posting to HCT/P establishments on COVID-19 (on hold)
 - March 19 – web posting for manufacturers of CBER-licensed biologics regarding changes in lot release
 - March 20 – Dr. Marks talked about blood supply on 50 states call
- CFSAN
 - Social media @FDAfood to notify about availability of food industry call on March 18
- CVM

- **Inspection delays / travel advisories (ORA)**

- **UFA deadlines at risk (ORA/Centers)**

- **Other cross-cutting**
- Daily - Prepared talking points for Commissioner Hahn for daily White House Task Force and press briefing
- Daily - Prepared/posted tweets/graphics on above topics for Commissioner and FDA accounts
- Weekly (Wednesdays): COVID-19 response recap emails to stakeholders (~65K)
- Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA
- March 19 –Consumer FAQs translated to Spanish & posted
- March 20 or 23 - FDA Voices on PHS All Hands/role in response
- March 20 or 23 - message to patients with cancer and their health care providers (Oncology Center of Excellence)
 - Date TBD - Comprehensive press statement on FDA response activities, to provide update on areas including diagnostics, inspections, and supply chain

- **Other comms?**
- Promoting WH, HHS, CDC, etc?

MEDIA MONITORING (Anne) - notes on SharePoint

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- White House press conference/TF
- AEG discussions
- Hahn NPR interview this morning

TODAY'S FOCUS DISCUSSION

- **Expectations for media inquiries, other deadlines (Lena/all)**
- **Internal comms regarding talking to outside entities (Lena)**
- **Hand sanitizers – add contact info to landing page? (Lena)**
- **Staffing (do you need help?)**
- **Strategy / forward look**
- Anything from OEA?

Pending, from previous discussions

- FDA outreach to diverse populations (Gloria Sanchez-Contreras, OMA)
- 3D printing issues (CDRH)
- Web language RE travel (“please be advised” box + home page blurb) – Heidi Rebello working on this

Other items for JIC discussion/reference:

- Info for daily WH press briefing – what #s, etc. do we need today?
 - Folder of WHTP
 - OL Q&A SP
- Other hot topics
 - Therapeutics
 - Food supply
 - Consumer inquiries

Reminder when sending review requests to JIC:

- Filename in SharePoint: (b)(4) (no spaces – e.g., 20200319_Blood_supply_stmt)
- Please insert the JIC clearance table at the end of your doc, so JIC & IMG members can quickly mark as reviewed (it lives in the JIC Process folder in SharePoint; also attached to 3/19 a.m. email)

Reviews

Note: This table includes mostly items still in JIC/IMG review, to help JIC/IMG members easily keep track of outstanding reviews. It is NOT a comprehensive list of all pending comms. (Short turnaround reviews that happen after ~4 p.m. with deadlines before ~9 a.m. the following day are not included.)

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Center(s) Responsible	Notes
White House TPs (folder – new location)	Daily by 12 pm (time may vary)	Stephanie Caccamo/ Carly McWilliams		All	Note: These do evolve and shift throughout the day as we are asked to add additional content.

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Center(s) Responsible	Notes
<u>InsideFDA FAQs for employees</u>	March 5	Tina Harrison	OGC/GLD (clearing OO/HR Q&As, at OCC request)		JIC reviews completed March 6; with Tania Tse for GLD clearance
<u>Consumer response letter</u>	TBD (revised letter)	April Finnen / Anne Norris	Rewriting		Rewrite to respond from RADM Hinton (ExecSec noted policy that Dr. Hahn does not respond to consumer letters; letter was written from Dr. POV).
<u>FDA Voices on PHS all hands/response support</u>	TBD	Brooke Leggin	HHS		Target date for publication is 20 Mar
<u>Reps. Rose and Reed letter on high throughput testing of COVID-19 Samples</u>	March 19 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Rep. Porter letter on COVID-19 testing</u>	March 20 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Sen. Thom Tillis letter on COVID-19 testing</u>	March 20 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Sens. Warren/Murray letter on including pregnant and lactating women in COVID-19 vaccine clinical trials</u>	March 23 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CBER, OMH, OWH	
<u>Rep. Perlmutter letter on antiviral drugs</u>	March 25 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER/CBER	
<u>E&C Oversight Nasal Swab Inquiry</u>	March 25 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Sen. Gardner letter re EUAs/testing</u>	March 25 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Sen. Blackburn drug inquiry</u>	March 26 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Center(s) Responsible	Notes
<u>Rep. Zeldin letter re COVID-19 testing</u>	March 26 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
<u>Rep. Beyer letter on COVID-19 testing</u>	March 30 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Rep. Carter letter on compounding</u>	March 30 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
<u>HGSAC Minority f/u briefing questions related to medical product supply chain</u>	March 25 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH, CDER, and ORA	
<u>Foreign Inspections/COVID-19 Questions from Briefing with bipar House E&C staff</u>	March 25 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH, CDER, and ORA	
<u>Food & Feed Inspection and Food Waste Q&A</u>	March 23 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CFSAN, CVM, and ORA	
<u>National Governors Association Questions re drug supply chain and diagnostics</u>	March 24 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH & CDER	
<u>Remdesivir question from Sen. Toomey's office</u>	March 23 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
<u>Follow up questions from E&C Briefing</u>	March 23 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
<u>IND Question from Congressional fellow</u>	March 26 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
FUTURE COMMS					
Daily tweets (including evergreen + weekends)	Daily before 3:00 p.m.	Abby Capobianco / Erin Ruberry		All	Ongoing: time-sensitive Commissioner tweets need to be AEG-cleared before 3:00 p.m. daily

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Center(s) Responsible	Notes
WORKING COPY of the TPs (this week)	NEW – daily by 3 p.m. JIC input	Siobhan DeLancey	JIC/IMG	All	

April Finnen

IMG JIC Lead

2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)

U.S. Food and Drug Administration

Desk: 240-402-0470

EOC: (b)(6) (hours at EOC: Mon. & Thurs. 9 a.m. – 11:30 a.m., 1 – 3 p.m.)

Cell: (b)(6) ← Call this # or IM/Skype to reach me

Email: april.finnen@fda.hhs.gov

JIC (Joint Information Center) email: 2019-nCoVFDAIMGJIC@fda.hhs.gov



From: Fisher, Robert [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=93FOCC92E98C4881BD675C3121B343BD-ROBERT.FISH]
Sent: 3/20/2020 10:04:28 AM
To: Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: TIME-SENSITIVE: question related to Battelle and MCMi
Attachments: 190930 ARA Final Report HHSF223201400158C - FINAL.pdf

Indeed. We did fund ARA to look at N95 decontamination, and people have been asking for a copy of the resulting report documenting the research (attached). Long story short...there was some concern about disseminating widely without knowing who was receiving it, but it is a public document and circumstances have shifted things in the direction of making it freely available. The report is attached.

I'm not aware of any recent interactions with the DepSec on this....but copying RADM Hinton and Michael Mair because they may have more visibility.

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Friday, March 20, 2020 09:59
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Cc: Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Subject: TIME-SENSITIVE: question related to Battelle and MCMi
Importance: High

Robert,

Do you recall from several years ago when we had an MCMi BAA solicitation regarding N95 decontamination to enable reuse whether we received a quad chart or a proposal from Battelle? Something sticks in my head but I cant recall the details.

I know we awarded contract to ARA/Brian Heimbuch for similar work but wasn't sure of the level of interaction we had with Battelle on their approach.

I ask because they are interacting with the DepSec Hargen and our SMEs in CDRH are now engaged in that discussion to determine if there is a viable reg path forward for them to proceed, and we have a call set up with them for 10:30am.

Apparently, they mentioned at the DepSec call interacting with OCET in the past and I have vague recollections as well, but not sure how much data we had ever seen and vetted.

Whatever insight you can provide would be helpful here.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO66, Room 5410
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Suzanne.Schwartz@fda.hhs.gov





Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

From: Thomas, Audrey A [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0E1250E3B21344CE89BD561FF8BAE53A-THOMASA]
Sent: 3/20/2020 10:16:10 AM
To: Wilson, Carolyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a78919ec52b7440e94f5928758847404-wilsonc]; Barratt, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a7a14bd5dcfd4121849b18beffcebbdb-BARRATTR]; Mendrick, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2be78d4cfe4c8fa2685b38cbdd6e25-DMendrick]; Kwan, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8c10cdb276014c4dae0b399f86ba64ff-Jonathan.Kw]; Braunstein, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd4eb429abb54b56ae58a84d1c0077ba-BraunsteinE]; Nugent, Bridget [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=304aba05001b40518bc37dce94044ff8-Bridget.Nug]; Ruiz, Juan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b773dc886c0d4dfba2ee6919f5cc80e5-Juan.Ruiz]; Johanson, Elaine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=636a76a574ab4d4498438b47493217bc-JOHANSONE]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Bright, Roselie A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4eef60c88912461ca085bcb876d3b45c-RXB]; Patel, Keyur [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=70077d1043dc4a8bb0ef774865deb60f-Keyur.Patel]; Schneider, Julie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9b938530b11846a29dca7d031cdf3d34-Julie.Schne]; Vasisht, Kaveeta [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=829ef402d6284b4aab60db92ebada1dd-VASISHTK]; Lee, Christine (OC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=46b2c2861a86482589389aee84448588-LEECHRI]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]; Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAJOR]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Margerrison, Edward [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=12386cee44f645b69f7215d42b265d70-Edward.Marg]; Saha, Anindita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f66659d5a8a4c6f8ffdbddccc7d312-AXS]; Fisher, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=93f0cc92e98c4881bd675c3121b343bd-Robert.Fish]; Orr, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc61d283504540b3bb0280413a8e8071-Robert.Orr]; MacGill, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af70ffa710334d5c972ef0f87f099f79-Tracy.Macgi]
CC: Blumkemelor, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7676a976c93642f985adabb1f7ef2db8-Donna.Blumk]; Zinn, Rebekah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=28f2489f571f4117971b764ce05a43a8-Rebekah.Zin]; Chada, Kinnera [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c6477a3fe02e40d7a6d7db5c40f92ba5-ChadaK]; Smith, Tara (CDRH)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f75e433d7e564d7e848c5284e3921326-Tara.Smith]; 'Giacomini, Kathy' (Kathy.Giacomini@ucsf.edu) [Kathy.Giacomini@ucsf.edu]; russ.altman@stanford.edu; Friciello, Maria (Maria.Friciello@ucsf.edu) [Maria.Friciello@ucsf.edu]; 'Lin, Lawrence' (Lawrence.Lin@ucsf.edu) [Lawrence.Lin@ucsf.edu]

Subject: RE: COVID19

Attachments: BAYVIRO COVID19 PROJECTS_RESOURCES.XLSX

FYI. Please find attached a table from UCSF-Stanford CERSI of the list of laboratories in the Bay Area that are working on COVID-19 related research. I am also including the link for this table in case you are able to open it. I was not. <http://cend.globalhealth.berkeley.edu/2020/03/16/3936/>

If you would like to connect with any of these investigators, you can reach out to them directly or you can contact Lawrence Lin at Lawrence.Lin@ucsf.edu (copied on this email) if you need assistance.

Thanks.

Audrey Thomas

From: Thomas, Audrey A

Sent: Monday, March 16, 2020 8:22 AM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>

Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'joseph.ross@yale.edu' <joseph.ross@yale.edu>; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>

Subject: RE: COVID19

More info on Mayo Clinic's new COVID-19 diagnostic test:

Mayo Clinic Launches COVID-19 Test; Results Within 24 Hours

- 13 Mar 2020
- NEWS



Executive Summary

Mayo Clinic is developing a test to detect COVID-19 in the US.

The Mayo Clinic said it developed a test that can detect the SARS-CoV-2 virus, which causes COVID-19, in various clinical samples. It is the latest in a growing arsenal of test developers in the US to help combat the spread of the disease.

On 12 March, the Mayo Clinic in Rochester, MN announced it developed a real-time polymerase chain reaction (PCR) test that can detect the novel coronavirus in specimens such as nasopharyngeal swabs, sputum, throat swabs, bronchoalveolar lavages and bronchial washings. Results are available within 24 hours, the Mayo Clinic reported.

The test has already been made available to health care providers. All positive samples will be sent to the Minnesota Department of Health or the Centers for Disease Control and Prevention for appropriate follow-up testing and confirmation. The test results will be communicated with public health officials.

"This test should help ease some of the burden that is currently being felt at the Centers for Disease Control and Prevention (CDC) and state public health laboratories," said William Morice II, president of Mayo Clinic Laboratories, which is the global reference laboratory of Mayo Clinic. "We are doing everything we can to help relieve the burden during this time to provide answers for patients here in Rochester and around the world."

Sharon Theimer, a spokesperson for the Mayo Clinic, said that the clinic can provide 200 to 300 tests per day. She anticipates "that the demand will exceed capacity and will be ramping up as soon as new equipment arrives."

On 11 March, the Mayo Clinic also started a "drive-through" process in Rochester to test patients who were directed to the location by the clinic after they have been screened by phone. Theimer could not provide details on how many patients have been tested at the location thus far.

The large hospital-affiliated reference lab is joining the ranks of some of the biggest diagnostic companies – NeuMoDx Molecular Inc., Qiagen NV, Quest Diagnostics Inc., and Laboratory Corp. of America Holdings – that also started providing health care providers with tests to detect COVID-19.

An \$8.3bn "Coronavirus Preparedness and Response Supplemental" funding act, approved by US Congress last week and signed into law on 6 March seeks to assist state and local health departments in fighting the spread of the virus. Under the supplemental funding bill, the US Food and Drug Administration will receive \$61m to prevent, prepare for and respond to the coronavirus. (Also see "\$8.3Bn Coronavirus Response Act Lays Out US FDA's, CDC's And Localities' Roles In Fighting Virus" - Medtech Insight, 10 Mar, 2020.)

Testing Capacity Challenges

Despite ongoing efforts by companies and federal and state agencies to develop tests, the capacity to test people for the illness remains one of the biggest challenges in the US, and testing capacity varies widely across the

country. (Also see "US CMS Providing Medicaid Coverage For COVID-19 Tests, But Congressman Still Sees Gaps For Testing Working Poor" - Medtech Insight, 9 Mar, 2020.)

According to the CDC, as of 12 March there are 1,215 total cases of confirmed coronavirus cases in the US; and 36 reported deaths, reflecting the number of people tested at CDC's laboratory. The Covid Tracking Project, which combines efforts by the Related Sciences, a Denver-based venture creation firm, and journalists by *The Atlantic*, created a chart to update daily testing capacity for the coronavirus in all US states.

From: Thomas, Audrey A

Sent: Saturday, March 14, 2020 7:03 AM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>

Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'joseph.ross@yale.edu' <joseph.ross@yale.edu>; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>

Subject: RE: COVID19

FYI. Please find attached a one-pager from Mayo Clinic CERSI on Mayo's resources related to COVID-19. If you would like to connect with Mayo Clinic, please contact Nilay Shah at shah.nilay@mayo.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A

Sent: Monday, March 09, 2020 3:51 PM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>

Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>

Subject: RE: COVID19

FYI. Please find attached a one-pager from Yale University CERSI on Yale's resources related to COVID-19. If you would like to connect with the Yale University, please contact Joe Ross at joseph.ross@yale.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A

Sent: Sunday, March 08, 2020 7:03 PM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Russ B Altman <Russ.Altman@stanford.edu>; 'Giacomini, Kathy' (Kathy.Giacomini@ucsf.edu) <Kathy.Giacomini@ucsf.edu>; 'Lin, Lawrence' (Lawrence.Lin@ucsf.edu) <Lawrence.Lin@ucsf.edu>; Friciello, Maria (Maria.Friciello@ucsf.edu) <Maria.Friciello@ucsf.edu>

Subject: RE: COVID19

FYI. Russ Altman reached out to me to say that Stanford is in the middle of a crisis. They have a faculty member at the Med School that has tested positive for coronavirus. The school is moving to online classes along with other restrictions. I told Russ not to worry about my request.

I think that this will become more and more prevalent

(b)(6)

(b)(6)

Audrey

From: Thomas, Audrey A

Sent: Sunday, March 08, 2020 11:59 AM

To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; William Bentley <bentley@umd.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>
Subject: RE: COVID19

As requested, I have reached out to the CERSIs for information on their resources related to COVID-19. I just received a one-pager from the University of Maryland CERSI, Baltimore Campus. If you would like to connect with the University of Maryland, please contact James Polli at jpolli@rx.umaryland.edu (copied on this email).

Thanks.

Audrey Thomas

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>

Sent: Sunday, March 08, 2020 9:17 AM

To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@ihmi.edu>

Subject: RE: COVID19

Many thanks Audrey.

I shared with our CoV coordinator in CBER and we both think it would be great if you could reach out to each of the CERSIs with a similar request. Can't hurt to be more aware of all potentials out there.

Also, I'm assuming you are sharing the information with OCET as well.

Carolyn

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>

Sent: Sunday, March 8, 2020 7:25 AM

To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Blumkemeler, Donna <Donna.Blumkemeler@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@ihmi.edu>

Subject: FW: COVID19

Importance: High

FYI. As per discussion at Thursday's Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU's resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.

Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader

UCSF-Stanford CERSI Program Official (PO)

Office of Regulatory Science and Innovation (ORSI)

Office of the Chief Scientist

Office of the Commissioner

Food and Drug Administration

10903 New Hampshire Avenue

Bldg. 1, Rm 4220

Silver Spring, MD 20903

301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>

Sent: Saturday, March 07, 2020 8:46 PM

To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>

Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>

Subject: COVID19

Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins' resources that may be relevant to FDA's COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc:d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH's Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA's response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu

From: Schiller, Lowell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77949B06919E4F91AA788E9A616C50C7-LOWELL.SCHI]
Sent: 3/20/2020 10:37:17 AM
To: Jungman, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5238a0caec064ba8b5d598115bc4f99f-Elizabeth.J]; Throckmorton, Douglas C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fdc411a0b9be442daec5172d411e2fd3-THROCKMORTO]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; COVID-19 IMG [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3d6b2d87a8447f588a44999cb6b3490-COVID-19 IM]
CC: Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]
Subject: FW: Teva in the Fight Against COVID-19

FYI

From: Michael Brzica <Michael.Brzica@tevapharm.com>
Sent: Friday, March 20, 2020 10:28 AM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: Teva in the Fight Against COVID-19

Lowell:

I just wanted to make sure you [saw the news](#) that Teva is donating 6 million doses of hydroxychloroquine, a therapy used to treat malaria but has also shown some positive results when used off-label to treat COVID-19. I know FDA is considering adding COVID-19 as an acceptable indication when the science determines it's appropriate. We're ramping up production and anticipate having an additional 10 million doses in the channel within 30 days. And just to underscore this, Teva is providing this medicine at no cost to our buyers.

Teva is proud to play a critical role ensuring the nation's public health. In addition to hydroxychloroquine, Teva manufactures more than 500 medicines in 2,000 different dosage forms and strengths. In fact, Teva provides more than 10% of the nation's drug supply, providing American patients with approximately 1 out of 7 prescriptions they take. We manufacture these essential medicines in state-of-the-art manufacturing facilities across the country where we employ approximately 7,000 Americans.

Teva is committed to partnering with you as we work through these challenging times. And as we encounter issues and challenges on our own, I may be coming back to you with specific requests for help to ensure we can continue to do the critical work Teva is engaged in on behalf of the nation's health. If there's anything I can do for you in the meantime, please don't hesitate to let me know.

Stay well,

Michael.



Michael Brzica
Vice President | Government Affairs
+1 (202) 258-9499
Michael.Brzica@tevapharm.com | www.tevapharm.com

From: Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]
Sent: 3/20/2020 2:00:11 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
CC: Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
Subject: RE: Bicameral Hill Staff Briefing - Participant Line
Attachments: RE: Potential Bicameral Hill staff Call for Friday

See attached.

Thanks!!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, March 20, 2020 1:59 PM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Subject: RE: Bicameral Hill Staff Briefing - Participant Line

Please send talking points for reference – thank you

-----Original Appointment-----

From: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Sent: Thursday, March 19, 2020 5:49 PM
To: Pennington, Caitlin; Aguilar, Paul; Black, Jennifer; Gross, Karas; Hodnette, Jonathan; Lockheed, Matthew; Paulos, Lauren; Rath, Prakash (FDA); Schipper, Jodi; Tantillo, Andrew; Hinton, Denise; Raghuwanshi, Rakesh; Zembower, Jenna; Patel, Chaitali; 2019-nCoV FDA IMG Planning; Colonius, Tristan; Price, William; Feingold, Daniel; Luebke, Yasemin; Klimczak, Katherine
Cc: Aldridge, Megan; Measer, Gregory; Simms, Joshua; Malais, Tanya; Adleberg, Jill; George, Bryan; Lexer, Susan; Howard, Megan; Groat, Blaine *; Burns, Corey; Rosebraugh, Sydney
Subject: Bicameral Hill Staff Briefing - Participant Line
When: Friday, March 20, 2020 2:00 PM-2:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Dial-in: 1-888-606-9801; (b)(6)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/20/2020 2:03:19 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: INTERNAL, CONFIDENTIAL, DRAFT Reactive Responses - combined (3-20-20).docx
Attachments: Reactive Responses - combined (3-20-20).docx

From: Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]
Sent: 3/20/2020 2:12:35 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Potential Bicameral Hill staff Call for Friday
Attachments: Reactive Responses - combined (3-20-20) clean.docx

FYI – clean version if you need!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Friday, March 20, 2020 2:11 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

attached

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 2:07 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi Prakash -

Can you please send me a clean version without the various cross outs and edits?

Thanks,

Anand

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:35 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Apologies for the delay in sending this document. There was a deluge of information and postings yesterday, and we tried to capture and cut down the info. Everything here is OCC cleared and there shouldn't be any issue you haven't already seen or addressed. It's now alphabetized so hopefully easier to sift through.

For today's call, we received this update below from HHS on the speakers, and most notably the QA portion. Members will be asking questions. Given all the activity in the administration, this doesn't change our thinking regarding how many questions FDA may receive, which is 2-3 and possibly on therapeutics (chloroquine) and device shortages (swabs). If you have an opportunity, please plug the blood donation issue and the Commissioner and Dr. Marks have been doing yesterday and today.

I'll join you on the speaker line ahead of time, and not sure if folks will want to discuss any issues, but feel free to raise anything on who should answer what. Please let me know if you have a few minutes to talk.

Here is the line-up of briefers for this afternoon:

HHS: ADM Brett Giroir
ASPR:
CDC: Dr. Butler
FDA: Dr. Shah
NIAID: Dr. Andrea Lerner & Dr. Chase Crawford
CMS: Alec Aramanda

Again, the call in information is as follows:

Dial-in: 888-606-9801

Leader code: (b)(6)

Participant code: (b)(6)

Members will be on the line this week, and we have requested that only Members ask questions during the Q&A. Please plan to join the call 10 minutes early so the operator has ample time to activate all speaker lines. Let me know if you have any questions!

Thank you,

Prakash
202-868-2627

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:40 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi Prakash, Sounds great and thanks in advance for the reactive document. I won't need a prep for tomorrow. I really appreciate your help.
Anand

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:10 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi Dr. Shah,

We just confirmed again with HHS that only ASPR and Giroir will provide an update tomorrow. We'll make sure the reactive document we prepare for you will reflect everything that happened/is happening today. We'll plan to have that document for you tomorrow mid-morning.

Similar to last time, we expect a few FDA questions, with the focus on the domestic inspection issue and therapeutics. We know you've been focused on the response for many weeks now, but please let us know if you would like a prep and we can figure that out.

Thanks,
Prakash

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 3:30 PM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Great, thanks everyone

From: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Date: March 18, 2020 at 3:26:59 PM EDT
To: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi All,

Just wanted to follow up and confirm that this Friday's briefing is confirmed for 2 pm.

HHS has indicated that they would like an update from ADM Giroir's team and ASPR at the top on testing and PPE before moving in to the Q&A portion.

Thank you!

Caitlin

From: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:38 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

2-2:30 works, thank you!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:36 AM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>

Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Yes, sounds good

From: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:34 AM
To: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Potential Bicameral Hill staff Call for Friday

Hi Jenna & Dr. Shah,

We wanted to let you there may be a call on Friday, 3/20, at 2 pm. We are still working to confirm but wanted to provide a heads up. Does Dr. Shah have availability if this call does happen?

Thanks!

Caitlin

Caitlin M. Pennington, MSM
Special Assistant
Office of Legislation
Caitlin.Pennington@fda.hhs.gov
Direct line: 301-796-7064



From: Malais, Tanya [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
Sent: 3/20/2020 5:55:41 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]
Subject: 3-20-20 COVID-19 AEG Meeting Notes
Attachments: 3-20-20 COVID-19 AEG Meeting Notes.odt

Good evening,

Attached are my notes from the 3/20/20 AEG meeting.

Tanya E. Malais
Planning Section Chief
2019 Novel Coronavirus (nCoV) IMG
Office: 949-608-2984
Mobile: (b)(6)
Planning Section Email: (b)(6)
24 hour Emergency Number: 1-866-300-4374

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/20/2020 8:55:11 PM
To: MacGill, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af70ffa710334d5c972ef0f87f099f79-Tracy.Macgi]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Jones, Estella [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=99a7f2bd273d42e18320f0667688b0c1-Estella.Jon]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Millburne, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6378e887ca9a4bd7a4271652883cc8f6-Kenneth.Mil]; Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]
Subject: RE: PPE email text
Attachments: 190930 ARA Final Report HHSF223201400158C - FINAL.pdf

Dear Tracy,

Thank you for sending for review. I have no questions or concerns with the updated approach.

Best,

RADM Hinton

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Friday, March 20, 2020 8:30 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Millburne, Kenneth <Kenneth.Millburne@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Subject: FW: PPE email text
Importance: High

RADM Hinton,

As discussed this week, we've had a number of requests for the final project report for the MCMi BAA project Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness with Applied Research Associates. The two viable options considered, based on input from OCET and ORSI leadership and counsel, were to share the report using a CDA and including a disclaimer on the report or just sharing the report with the disclaimer. The current disclaimer on the attached report states:

"The data provided to you was generated by an FDA contractor. The FDA does not endorse or guarantee the efficacy of any method and/or data or potential applications described in the report. Additionally, the views expressed in this report are those of the authors and do not necessarily represent those of the U.S. Food and Drug Administration nor should they be interpreted as official Agency policy or guidance."

We decided to utilize the CDA and provided it to the four who had requested the report as of yesterday. Two were willing to use the CDA and two haven't responded. One of those (a physician), raised concerns about potential delays in getting the information to others by not allowing a recipient to share outside their institution and from a potential backlog in processing requests at FDA as the number of requests increase (we are seeing less time between requests).

(b)(5)

Please let me know if you have questions or concerns with the updated approach.

Best,

Tracy

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/21/2020 9:11:49 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: for IMMEDIATE review: ventilator PR

nope

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Saturday, March 21, 2020 8:52 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: for IMMEDIATE review: ventilator PR

See this one?

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 6:09 PM
To: CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: for IMMEDIATE review: ventilator PR

Hi folks—

Major revisions to the ventilator PR going today, I appreciate your urgent review in next hour.

OF NOTE—

(b)(5)

(b)(5)

Please help me in keeping this PR as lay person friendly as possible, while keeping it technically accurate. Thank you.

I appreciate your edits in sharepoint, but I'm copying whole PR below for awareness.

<http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/Ventilators%20guidance.docx>

(b)(5)

(b)(5)

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/21/2020 9:19:28 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: for IMMEDIATE review: ventilator PR

Hi Stephanie – please add Michal Mair for awareness.

Thank you,

Denise

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 6:09 PM
To: CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: for IMMEDIATE review: ventilator PR

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Major revisions to the ventilator PR going today, I appreciate your urgent review in next hour.

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(b)(5)

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I appreciate your edits in sharepoint, but I'm copying whole PR below for awareness.

<http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/Ventilators%20guidance.docx>

(b)(5)

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/22/2020 9:39:33 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Information for WHTF March 22.docx
Attachments: Information for WHTF March 22.docx

Now I'm left off too - life's too short! Happy Sunday!

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Date: March 22, 2020 at 7:50:45 AM EDT
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: Information for WHTF March 22.docx

Attached.

From: McWilliams, Carly
Sent: Sunday, March 22, 2020 7:44 AM
To: Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov) <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Information for WHTF March 22.docx

Good Morning,

Attached is information for the TF meeting today. Includes info on ventilator guidance and chloroquine supply. CCI is in red

Thanks,

Carly

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/22/2020 10:07:24 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Information for WHTF March 22.docx
Attachments: Information for WHTF March 22.docx

I understand why I am not included (not senior leadership worthy) and have given up trying. But u might endeavor to keep yourself in the loop.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Sunday, March 22, 2020 7:44 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Information for WHTF March 22.docx

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Carly

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/22/2020 11:21:10 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: COVID-19 & Azithromycin

Thanks Michael.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Sunday, March 22, 2020 11:13 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: FW: COVID-19 & Azithromycin

Denise – just for your awareness. The tweet below has been raised within context of the fraudulent products group.

More broadly, I suppose “...be put in use IMMEDIATELY” could be taken to mean under an appropriately designed clinical trial - however I don’t know whether there have been any conversations within leadership regarding providing additional context for this tweet.

This study is mentioned in the Information for Clinicians on Therapeutic Options for COVID-19 Patients just posted on CDC website.

“One small study reported that hydroxychloroquine alone or in combination with azithromycin reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit [7]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias.”

From: Link, Diana <Diana.Link@fda.hhs.gov>
Sent: Saturday, March 21, 2020 11:58 AM
To: Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Flynn, William T <William.Flynn@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Schell, Timothy <Timothy.Schell@fda.hhs.gov>; 2019-nCoV FDA IMG Operations Fraudulent Products <2019-nCoV-FDA-IMG-Operations-Fraudulent-Products@fda.hhs.gov>
Cc: Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Vengris, Vitolis E <Vitolis.Vengris@fda.hhs.gov>; Hart, Ellen <Ellen.Hart@fda.hhs.gov>
Subject: COVID-19 & Azithromycin

Hi all,

This tweet was posted this morning. I wanted to make you aware, in case this turns into the same issue we had with chloroquine. Right now I don’t see azithromycin available on eBay or Amazon, but this might change quickly and we could see azithromycin for fish and/or birds popping up. I do see it for sale on other smaller shop internet storefronts for birds and fish, but prices have not spiked yet.

Seeking input on whether we want to be proactive and have ORA Health Fraud (Jason Humbert) request that Amazon and eBay be aware of this and create filters and/or monitor.

- There are no FDA-approved animal products containing azithromycin
- Azithromycin is not an Indexed drug
- FDA-approved azithromycin for humans is a prescription drug

Diana



Donald J. Trump ✓
@realDonaldTrump



HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine. The FDA has moved mountains - Thank You! Hopefully they will BOTH (H works better with A, International Journal of Antimicrobial Agents).....

10:13 AM · Mar 21, 2020 · Twitter for iPhone

33K Retweets **108.1K** Likes



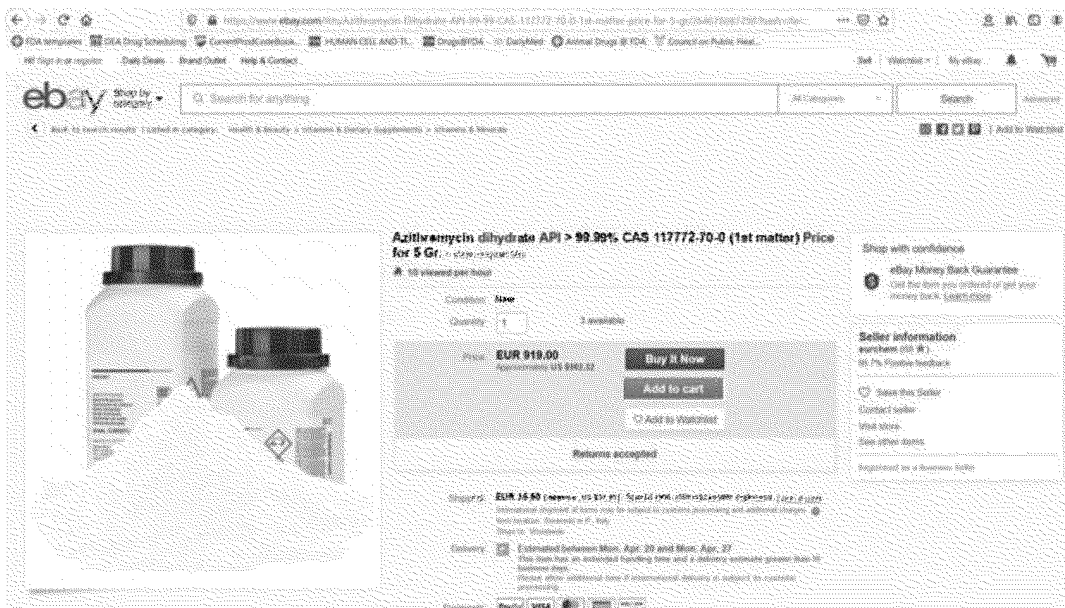
From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/22/2020 3:54:30 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: COVID-19 & Azithromycin

From: Link, Diana <Diana.Link@fda.hhs.gov>
Sent: Sunday, March 22, 2020 2:05 PM
To: Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Flynn, William T <William.Flynn@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Schell, Timothy <Timothy.Schell@fda.hhs.gov>; 2019-nCoV FDA IMG Operations Fraudulent Products <2019-nCoV-FDA-IMG-Operations-Fraudulent-Products@fda.hhs.gov>
Cc: Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Vengris, Vitolis E <Vitolis.Vengris@fda.hhs.gov>; Hart, Ellen <Ellen.Hart@fda.hhs.gov>
Subject: RE: COVID-19 & Azithromycin

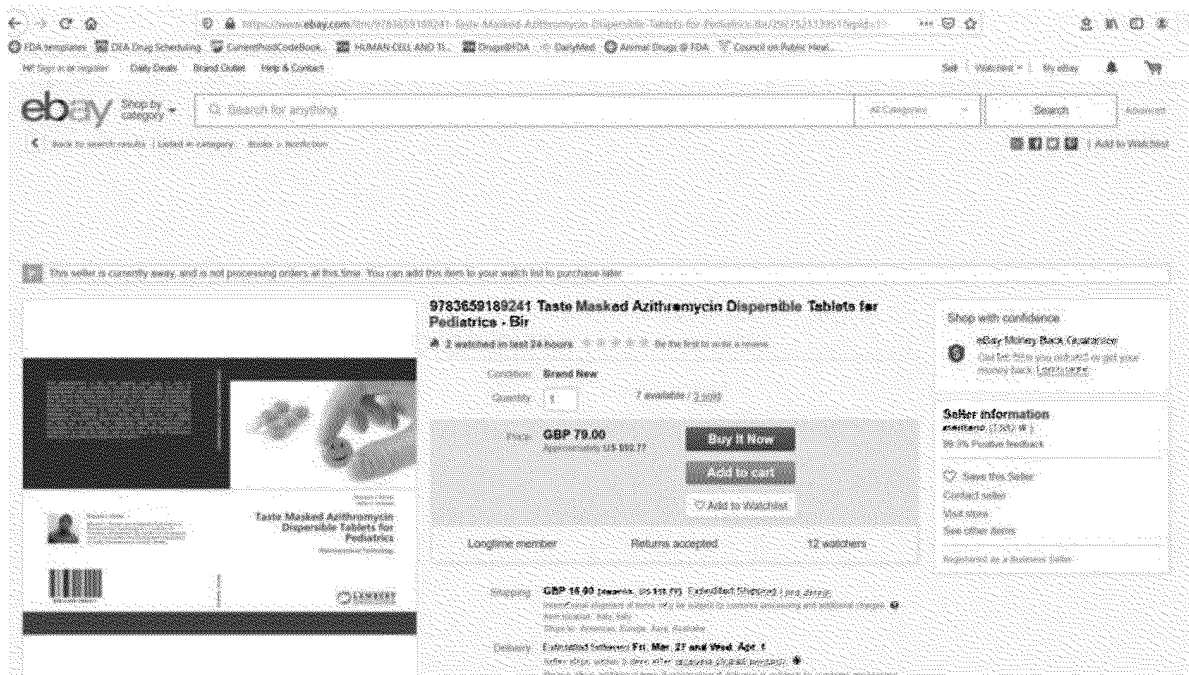
Hi all,

What happened with chloroquine is now happening with azithromycin. This appears to be out CVM's hands now, and I believe may be more appropriate for CDER. I will discontinue including CVM leadership on these e-mails unless told otherwise. I have not yet found price increases on azithromycin labeled for birds and fish.

These are shipping internationally with conversions to the US dollar on the listing, and are on U.S. ebay.



<https://www.ebay.com/itm/Azithromycin-Dihydrate-API-99-99-CAS-117772-70-0-1st-matter-price-for-5-gr/264676087298?hash=item3d9fec9602:g:9j0AAOSwh65ed31W>



<https://www.ebay.com/itm/9783659189241-Taste-Masked-Azithromycin-Dispersible-Tablets-for-Pediatrics-Bir/292752113951?epid=1937498802&hash=item442962c11f:g:r-wAOSwe~Bbsb3M>

Diana

From: Link, Diana

Sent: Saturday, March 21, 2020 11:58 AM

To: Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Flynn, William T <William.Flynn@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Schell, Timothy <Timothy.Schell@fda.hhs.gov>; 2019-nCoV FDA IMG Operations Fraudulent Products | (b)(6)

Cc: Bataller, Neal <Neal.Bataller@fda.hhs.gov>; Vengris, Vitolis E <Vitolis.Vengris@fda.hhs.gov>; Hart, Ellen <Ellen.Hart@fda.hhs.gov>

Subject: COVID-19 & Azithromycin

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- Azithromycin is not an Indexed drug
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10:13 AM · Mar 21, 2020 · Twitter for iPhone

33K Retweets **108.1K** Likes



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/22/2020 10:36:55 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: WHTF meeting background 3/23
Attachments: 2020.03.23 Background from WH Task Force Meeting final.docx

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Sunday, March 22, 2020 10:31 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: WHTF meeting background 3/23

Please see attached.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/23/2020 8:17:46 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

Okay – will shore up with Janice – thank you

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:17 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: Update 1.2: Schedule for Monday, March 23rd

Whatever works with schedule. 11:30 is great.

Sent from my iPhone

On Mar 23, 2020, at 8:10 AM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Janice asked for 1130 so would you like 1100 or 1130?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 7:24 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: Update 1.2: Schedule for Monday, March 23rd

Task force is at 4pm today. So 11 am AEG?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 23, 2020 at 6:46:32 AM EDT
To: "Olivarria, Frank" <Frank.Olivarria@fda.hhs.gov>
Cc: "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Shah, Anand" <Anand.Shah@fda.hhs.gov>, "Rom, Colin" <Colin.Rom@fda.hhs.gov>, "Copeland, Jakea" <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

Or also move AEG to 11 and we can do the media prep from 12 to 1:30?

Thanks

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Date: March 22, 2020 at 10:49:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand

<Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

2020.03.23 Background from WH TF Meeting, has been updated since the 10:39 PM message:

Denise: *one edit re: ventilator guidance, below:*

- **Ventilator supply strategies for HCPs guidance**

FDA will issued an immediately in effect guidance on March 22 to provide a policy for expanding the availability of ventilators and accessories as well as other respiratory devices during the COVID-19 pandemic.

Attached (updated doc).

From: Olivarria, Frank

Sent: Sunday, March 22, 2020 10:39 PM

To: Hahn, Stephen (SH1@fda.hhs.gov) <SH1@fda.hhs.gov>

Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>

Subject: Update 1: Schedule for Monday, March 23rd

Updates in **green**.

Your first call is scheduled for 7:10 AM: Quick Touch Point: Media[Stephanie Caccamo will call your cell] (your first in-person will be at 10:30 AM at HHS, you will be at HHS until 2 PM, when you depart for the WH, and you will return back to HHS by 7:50 PM for Remote Media Interview with Tucker Carson [from the HHS Studio])

7:10-7:15 am Quick Touch Point: Media

Note: Materials attached. POC: Stephanie Caccamo will call you (her number is: (b)(6))

7:15-7:30 am Telecon: Radio Interview - Boston radio: The Kuhner show

Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: Brittney Jennings: (b)(6) NLT 7:15 AM

7:30-7:45 am Telecon: Radio Interview - Steve Gruber Show, Flint, Michigan

Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: Ivey: (b)(6) (b)(6) NLT 7:30 AM

7:45-7:55 am Telecon: Radio Interview - Bloombdaddy (David), Pittsburgh, Host: BLOOMDADDY (DAVID)

Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: (b)(6) (back up just in case): (b)(6) NLT 7:45 AM

8:00-8:30 am TELECON ONLY: Commissioner's Daily Check-In

Note: Dial-In (1-877-465-7975,, (b)(6) #)

10:00 am Uber to HHS

10:30-12:00 pm Media Prep: Tucker Carlson Interview

Note: Location – HHS Studio (pending confirmation from Laura, otherwise will be in FDA Suite). Materials attached, same as 7:10 AM: Quick Touch Point: Media call.

10:00-12:00 pm HOLD: White House Buffer

12:00-1:00 pm COVID-19 AED Meeting

Note: Dial-In (1-877-465-7975,, (b)(6) #)

2:00 pm Travel to WH

2:00-2:30 pm Telecon: Weekly CFSAN Meeting with the Commissioner

Note: Agenda attached. Dial-In (1-877-465-7975,, (b)(6) #). You will take this call en route to the WH, however we are attempting to move the call up to 1:15 PM to avoid you having to take this en route – will text you and Colin if this changes.

2:30-3:00 pm Clear White House Security

3:00-3:30 pm Telecon: Senator Richard Durbin and Commissioner Hahn

Note: You will take this call at the WH, so avoid taking it en route to the WH. Materials attached, additional TP's on COVID-19 forthcoming. Dial-In (1-888-913-9943,, (b)(6) #).

3:30-4:00 pm Telecon: Bi-Weekly Check-In: AAbernethy / Dr. Hahn

3:50 pm Walk to WHSR for WHTF Meeting

4:00-5:00 pm White House Coronavirus Task Force Meeting

Note: Agenda and seating chart forthcoming. Janice will forward once received.

5:00 pm Travel to TBD (HHS or Residence)

6:00-6:30 pm Daily Check-In

Note: Dial-In (1-877-465-7975)

7:15 pm Travel to HHS (from residence, if not already at HHS)

7:45 pm Walk to HHS Studio

8:00-8:30 pm Interview (Remote): Tucker Carlson

Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. The interview will be for

.....

Reading Material(s):

1. nCoV Outbreak SITREP: March 22, 2020, attached
2. 2020.03.23 Background from WH TF Meeting, attached

.....

Calendar Snapshot:

<image001.png>

.....

All Materials: [LINK](#)

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/23/2020 3:29:56 PM
To: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]
Subject: RE: Question re: FEMA Address

Thank you for your quick response!

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Question re: FEMA Address

Yes – the address is Covidsupplies@fema.dhs.gov and the site is <https://www.fema.gov/coronavirus/how-to-help>.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:19 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Question re: FEMA Address

Hi Andrew,

Would you please send the final contact reference document you worked on over the weekend? In it, you wrote the legislation fda address would be replaced with the FEMA address. Do you have that address for reference?

Companies seeking to Import, Donate, or Manufacture Medical Products to Aid the U.S. Response to COVID-19: If a constituent company would like to import, donate, or produce medical products to help with the COVID-19 response such as personal protective equipment, swabs, etc., please send these inquiries to legislation@fda.hhs.gov. Please include as many details as possible about the request and contact information for the company, either an agent in the U.S. or the company itself. This information is necessary for us to respond and get you and your constituents the additional information you need.

Thank you,

Denise

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 3/23/2020 3:30:47 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: FYSA: Question re: FEMA Address

But that address is not for donations. I gave that one to him below earlier today. So just wanted to talk for a minute about best approach.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:30 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FYSA: Question re: FEMA Address

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Question re: FEMA Address

Yes – the address is Covidsupplies@fema.dhs.gov and the site is <https://www.fema.gov/coronavirus/how-to-help>.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:19 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Question re: FEMA Address

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Companies seeking to Import, Donate, or Manufacture Medical Products to Aid the U.S. Response to COVID-19: If a constituent company would like to import, donate, or produce medical products to help with the COVID-19 response such as personal protective equipment, swabs, etc., please send these inquiries to legislation@fda.hhs.gov. Please include as many details as possible about the request and contact information for the company, either an agent in the U.S. or the company itself. This information is necessary for us to respond and get you and your constituents the additional information you need.

Thank you,

Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/23/2020 3:44:49 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Biofire EUA
Attachments: 2-EUA200044 Biofire LOA_03232020.doc; 4-EUA200044 Biofire Patient FS.docx; 3-EUA200044 Biofire HCP FS.docx; 2-EUA200044 Biofire LOA_03232020_.pdf
Importance: High

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, March 23, 2020 11:13 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Biofire EUA
Importance: High

The BioFire EUA is ready for signature.
Michael will no longer be clearing the IVD ones, so it's good to go from OCET. Thanks, Liz

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: Johanson, Elaine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=636A76A574AB4D4498438B47493217BC-JOHANSONE]
Sent: 3/25/2020 2:41:45 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]
Subject: FW: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial

Elaine Johanson

Director, Office of Health Informatics (Acting)

Office of the Chief Scientist
Office of Health Informatics
U.S. Food and Drug Administration
Tel: 301-796-7315
elaine.johanson@fda.hhs.gov



From: Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 1:52 PM
To: OHI <OHI@fda.hhs.gov>
Subject: Fyi: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial

From: Lewandoski, Mark (NIH/NCI) [E] <lewandom@mail.nih.gov>
Sent: Wednesday, March 25, 2020 1:12 PM
To: Bright, Roselie A. <Roselie.Bright@fda.hhs.gov> (b)(6)
Subject: FW: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial

From: NIH Executive Secretariat (b)(6)
Date: Wednesday, March 25, 2020 at 1:10 PM
To: List NIH-ALL-STAFF (b)(6)
Subject: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial
Resent-From: (b)(6)

Dear NIH Family:

Last night the NIH Clinical Center enrolled its first two research participants with COVID-19 as part of the National Institute of Allergy and Infectious Diseases (NIAID) randomized, controlled clinical trial of the antiviral remdesivir. The patients were transported from Suburban Hospital and placed in the Special Clinical Studies Unit (SCSU), a highly specialized infectious disease containment and treatment facility within the hospital. This facility was successfully used from 2014 to 2016 to care for patients with Ebola Virus Disease and is used for many other infectious disease trials. This is yet another way that NIH is playing a critical role in addressing the challenge of COVID-19.

The NIH Clinical Center is specially equipped to handle patients with highly infectious diseases, including high-level respiratory isolation capabilities and highly trained infectious diseases and critical care specialists. These staff have been prepared to receive research participants and have implemented strict infection control practices optimized to prevent spread of potentially transmissible agents such as the novel coronavirus from an infected patient either to health care personnel or to the surrounding hospital environment.

NIAID announced the launch of the trial on February 21, 2020, at the University of Nebraska Medical Center in Omaha. Since then more than 37 study locations have been added, including the NIH Clinical Center. The trial is evaluating the safety and efficacy of remdesivir in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement, including abnormal sounds heard through the stethoscope when breathing (rales) with a need for supplemental oxygen, abnormal chest X-rays, or inadequate oxygenation requiring mechanical ventilation. Individuals with confirmed infection who have mild, cold-like symptoms or no apparent symptoms will not be included in the study. The trial sites are enrolling participants quickly and we are hopeful that an answer on safety and effectiveness will be reached this spring.

I think we're all anxious for the development of safe and effective vaccines and treatments for this highly infectious strain of coronavirus. Currently, however, mitigation and containment remain our best options for reducing community spread of the infection. I want to thank you for your support of the physical distancing measures that have been put in place at NIH. I know it's not easy, but we will get through this together.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director, NIH

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/25/2020 3:41:35 PM
To: Welch, Alice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82d5f547db694aa2a2c6f51ca5a085b1-Alice.Welch]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; MacGill, Tracy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=af70ffa710334d5c972ef0f87f099f79-Tracy.Macgi]
CC: Millburne, Kenneth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6378e887ca9a4bd7a4271652883cc8f6-Kenneth.Mil]
Subject: RE: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial

Thanks for sharing, Alice!

From: Welch, Alice <Alice.Welch@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 2:11 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Cc: Millburne, Kenneth <Kenneth.Millburne@fda.hhs.gov>
Subject: FYI: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial

Alice
Office (301) 796-8449
Mobile (b)(6)
Fax (301) 847-3539

Notice: This message, together with any attachments, contains information that may be confidential, proprietary and/or legally privileged and is intended solely for the use of the individual or entity named above. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, or copying of this message or its content is strictly prohibited. If you have received this message in error, please notify sender immediately and delete the message without making a copy. Thank you.

From: NIH Executive Secretaria (b)(6)
Sent: Wednesday, March 25, 2020 1:08 PM
To: List NIH-ALL-STAFF (b)(6)
Subject: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID Remdesivir Trial

Dear NIH Family:

Last night the NIH Clinical Center enrolled its first two research participants with COVID-19 as part of the National Institute of Allergy and Infectious Diseases (NIAID) randomized, controlled clinical trial of the antiviral remdesivir. The patients were transported from Suburban Hospital and placed in the Special Clinical Studies Unit (SCSU), a highly

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Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director, NIH

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/26/2020 10:12:47 AM
To: Fortney, Russell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86db918272164d9ea5d88d0dc8721f10-FORTNEYR]
Subject: RE: WSJ on Safe and Effective

Thanks

From: Fortney, Russell <Russell.Fortney@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:19 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FYI: WSJ on Safe and Effective

FDA Shouldn't Keep Safe Drugs off the Market

Congress's mandate that medications be proved effective is unnecessary and delays potential cures.

By
Charles L. Hooper and
David R. Henderson
March 25, 2020 6:28 pm ET



A laboratory technician prepares Covid-19 patient samples for testing in Lake Success, N.Y., March 11.

Photo: John Minchillo/Associated Press

The federal government requires pharmaceutical companies to prove that their drugs are both safe and effective before putting them on the market. Before 1962, companies needed to prove only safety. While there is some appeal to this two-hurdle approach, evidence suggests that there is only a slight benefit and a tremendous cost. With the Covid-19 pandemic sweeping the world, there has never been a better time to revoke the Food and Drug Administration's efficacy requirement.

The thinking behind the FDA's two-hurdle approach is that ineffective drugs cost money and impose an opportunity cost: While the ineffective drug is being used, potentially effective ones are not. But researchers who have studied the 1962 law, known as the Kefauver-Harris Amendments, have concluded that before it was enacted, ineffective drugs were a small percentage of the market and therefore not much of a problem.

Further, the Kefauver-Harris Amendments dramatically increased the time and cost of getting new drugs approved. Evidence provided by University of Chicago economist Sam Peltzman suggests that the number of new drugs approved dropped by 60% in the decade following the law change. We have fewer ineffective drugs, but also far fewer effective ones than we could have had.

That's not all that's wrong with the Kefauver-Harris Amendments.

Before 1962, patients and doctors needed to try drugs to see if they worked for a particular patient at a particular time. It's called trial and error and, despite the change in law, is still the standard medical approach.

To understand how little the FDA's two-hurdle approach contributes, consider Merck's Keytruda (pembrolizumab), which has recently become one of the hottest drugs on the market. Keytruda got some good press after Jimmy Carter, who was suffering from melanoma, was diagnosed as cancer-free after taking it. Mr. Carter was lucky because in one clinical trial Keytruda destroyed or reduced the tumors in only 34% of patients. Keytruda—which was the fourth biggest-selling drug globally in 2018 and brought in worldwide revenues of \$11.1 billion last year—is far from a sure thing.

Does the FDA, which approved Keytruda as safe and effective for melanoma, know which patients will benefit from it? No. The potential benefits described on the drug's label are what happened to strangers in another time and place. Patients still have to try Keytruda to know if it will help *them*. An FDA approval for efficacy is largely duplicative.

Enter Covid-19, the disease caused by the new coronavirus, SARS-CoV-2. There are no proven therapies to treat an infection of that virus. One of the most promising candidates is Gilead Sciences' remdesivir, which has shown some potential in treating other coronaviruses, such as SARS and MERS. Due to its use in treating Ebola infections, remdesivir is known to be generally safe.

With the FDA's two-hurdle requirement in place, however, remdesivir must be proven effective in clinical trials before it can be sold for widespread use in Covid-19. These clinical trials take time, and they still won't answer many of the questions doctors have about the drug's use against Covid-19 now. What's the right dose to get remdesivir into the lungs? How early should it be given? If it is given to sick patients already on ventilators in hospitals, will it help? All these things will depend on the individual patient.

And then, even if remdesivir is approved by the FDA, patients and doctors will still resort to trial and error, because the success rate won't be 100%.

Instead, the FDA should allow patients and doctors to try remdesivir today. We know it's safe, and there are no other proven therapies. With more widespread usage, the medical community will have a tool to fight back against Covid-19. Controlled clinical trials can continue largely as they normally would. Though access to an experimental therapy won't be an incentive to join a clinical trial, many others remain—such as excellent free care and a sense of pride in helping society and other patients. This two-pronged approach would not only potentially save thousands of lives but also provide much more information.

If you were diagnosed with Covid-19 today, would you choose to take nothing? Or would you want a safe drug that has shown some potential against the virus? We suspect the great majority of Covid-19 patients would choose the latter option. And they would get it today, not months from now, when it would be of no use to them.

This same process plays out every day with other conditions that can be more dangerous than Covid-19. While patients and doctors continue to resort to trial and error out of necessity, the government insists that they initiate their experiments only after the FDA has completed its. This is a critically flawed approach to medicine.

Even as the pandemic robs Americans of their jobs, health and lives, it could reward us with a silver lining if we use the opportunity to take a hard look at our drug-approval process. Revoke the FDA's drug-efficacy requirement.

Mr. Hooper is president of Objective Insights Inc., a company that consults for life-science companies. Mr. Henderson, a research fellow with the Hoover Institution, was senior health economist with President Reagan's Council of Economic Advisers.

Sent: 3/26/2020 10:44:21 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
Subject: RE: chloroquine eua

Thanks Janet, Keagan, and Stacy. If agreed, Liz Sadove can work with Jacqueline

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 26, 2020 10:25 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: chloroquine eua

I believe Jaqueline is leading, correct Janet? Can we filter things to her, or do you want another lead?

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Thursday, March 26, 2020 10:16 AM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: chloroquine eua

I have reached out to Rick Bright and we will get organized with him. (b)(5)
(b)(5)
(b)(5) Janet W

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Thursday, March 26, 2020 10:14 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: chloroquine eua

I cannot emphasize enough that we need someone to lead this project and (b)(5)
(b)(5) Jeet has contact info for everyone at ASPR, CDC, and BARDA working on this.

I know this is outside my swim lane to be directing folks re this and I know everyone is doing their best. (b)(5)
(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:35 AM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eua

Do we have anyone to ask at CDC?

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>

Sent: Thursday, March 26, 2020 8:29 AM

To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

Subject: RE: chloroquine eua

Just to clarify,

(b)(5)

(b)(5)

--
Jeet Guram, M.D.

Senior Advisor, Office of the Commissioner

Food and Drug Administration

+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>

Sent: Thursday, March 26, 2020 8:21 AM

To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

Subject: RE: chloroquine eua

Hi

(b)(5)

Thanks

Jacqueline

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>

Sent: Thursday, March 26, 2020 8:15 AM

To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

Subject: RE: chloroquine eua

Fyi, (b)(5)

(b)(5)

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:21 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eua

That is helpful

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:21 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eua

Fyi, Stacy sent an email to a broader group with HHS and ASPR/BARDA to confirm that

(b)(5)

(b)(5)

(b)(5)

I'll keep this group posted on what

we hear.

--

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: chloroquine eua

(b)(5)

(b)(5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>

Sent: Wednesday, March 25, 2020 9:56 PM

To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>

Subject: RE: chloroquine eua

(b)(5)

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>

Sent: Wednesday, March 25, 2020 9:28 PM

To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>

Subject: RE: chloroquine eua

(b)(5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>

Sent: Wednesday, March 25, 2020 8:22 PM

To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

Subject: chloroquine eua

Fyi.

(b)(5)

(b)(5)

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Sent: Wednesday, March 25, 2020 7:50 PM

To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>;

Gormley, Nicole <Nicole.Gormley@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Subject: RE: HHS distribution of HCQ from Pharma Cos.

(b)(5)

(b)(5)

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>

Sent: Wednesday, March 25, 2020 6:57 PM

To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Gormley, Nicole <Nicole.Gormley@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>

Subject: FW: HHS distribution of HCQ from Pharma Cos.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Wednesday, March 25, 2020 6:56 PM

To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>

Subject: Fwd: HHS distribution of HCQ from Pharma Cos.

This is what another part of HHS says—see below. Jw

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

Date: March 25, 2020 at 6:46:00 PM EDT

To: Hamel, Joseph (OS) <Joseph.Hamel@hhs.gov>, Kane, Elleen (OS) <Elleen.Kane@hhs.gov>, ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>

Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Subject: RE: HHS distribution of HCQ from Pharma Cos.

+ Janet Woodcock

Patrizia

From: Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>

Date: March 25, 2020 at 6:37:41 PM EDT

To: Kane, Elleen (OS) <Elleen.Kane@hhs.gov>, ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>

Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

Subject: RE: HHS distribution of HCQ from Pharma Cos.

Per Gary's last note

(b)(5)

(b)(5)

Strategic Innovation and Emerging Technology Manager

Assistant Secretary for Preparedness and Response

Office: 202-969-3852

Cell: (b)(6)

From: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>

Sent: Wednesday, March 25, 2020 6:35 PM

To: ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: RE: HHS distribution of HCQ from Pharma Cos.

Joe, checking back on accuracy here. Thanks!

From: Kane, Eileen (OS/ASPR/OEA)
Sent: Wednesday, March 25, 2020 3:32 PM
To: ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: FW: HHS distribution of HCQ from Pharma Cos.

I talked with Joe Hamel about this. Here's what I propose as a response.
Joe, can you check accuracy?

(b)(5)

Thank you!

Vr, Eileen

From: Marcy O'Koon <mokoon@arthritis.org>
Sent: Wednesday, March 25, 2020 3:21 PM
To: ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>
Subject: HHS distribution of HCQ from Pharma Cos.

Hi- I am from the Arthritis Foundation national office. We have been keeping our constituents informed as the coronavirus crisis unfolds. A very hot topic right now is the shortage of hydroxychloroquine. I understand that the distribution or allocation (?) of the quantity that Novartis is donating, above its normal production, is being handled by HHS. I would like to talk to someone about that. Are you the right one? If not, can you connect me with someone who can help?

This is an urgent matter for us and have copy live on the website that we are updating, so would appreciate a quick reply (although I understand how crazy-busy you all must be).

Thank you.

Marcy
Cell: (b)(6)

Marcy O'Koon
Arthritis Foundation
Senior Advisor, Consumer Health | Home Office
1335 Peachtree St., NW, Suite 600 | Atlanta, GA 30309
404.965.7616 | moko●n@arthritis.●rg



arthritis.org



From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/27/2020 1:46:30 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FYSA: EUA Distribution Authorization Letter - SMD
Attachments: EUA Distribution Authorization Letter - SMD.pdf

From: (b)(6)
Sent: Friday, March 27, 2020 12:53 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; CVSDBadmin@cdc.gov
Cc: CDRH-NonDiagnosticEUA-Templates <CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov>
Subject: EUA Distribution Authorization Letter - SMD

Dear Ms. Hinton

Please find attached a letter requesting authorization pursuant to the EUA issued on March 2, 2020 to distribute N95, KN95 and other PPEs to help combat the COVID-19 outbreak in the US. We have attached our credentials as a medical device company and a list of our current providers of masks and potentially other PPEs. In an effort to assure a speedy delivery of the products, we are also proposing to ship directly to the facilities in need. We will keep accurate records of all transactions and have provisions to handle complaints and reports MDRs as required by the EUA.

Thank you for your time and effort in this matter.

Regards,

(b)(6)

Director QA/RA

(b)(4)

(b)(6) (cell)

From: O'Shaughnessy, Jacqueline A [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3FCC0BBFC81941E497313B309196F28B-OSHAUGHNESS]
Sent: 3/28/2020 3:16:21 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients
Attachments: N-95_VHP-Decon-Re-Use.pdf; Re: Hydrogen Peroxide decon of PPE

FYI

From: Gump, Robert <Robert.Gump@fda.hhs.gov>
Date: March 28, 2020 at 2:13:53 PM EDT
To: Finnen, April <April.Finnen@fda.hhs.gov>, 2019-nCoV FDA IMG JIC Leadership <2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov>
Cc: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Subject: FW: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients

FYI... shared with our animal programs:

(b)(5)

Bob Gump, BS, CMAR
Interdisciplinary Scientist/Biologist
FDA/OC/OCS/OCET

O: 301-796-0205

C: (b)(6)

From: Gump, Robert
Sent: Saturday, March 28, 2020 2:04 PM
To: Dennis, John <John.Dennis@fda.hhs.gov>; Gonzales, Raoul <Raoul.Gonzales@fda.hhs.gov>; Mack, Pamela <Pamela.Mack@fda.hhs.gov>; Tinaza, Constante <Constante.Tinaza@fda.hhs.gov>; Ferrine, Anthony <Anthony.Ferrine@fda.hhs.gov>; Moran, Kellie <Kellie.Moran@fda.hhs.gov>; Evans, Eric <Eric.Evans@fda.hhs.gov>; Reed, Kevin J <Kevin.Reed@fda.hhs.gov>; Prince, Kahrin <Kahrin.Prince@fda.hhs.gov>
Cc: Jones, Estella <Estella.Jones@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>; Skinner, Brianna <Brianna.Skinner@fda.hhs.gov>
Subject: FW: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients

(b)(5)

(see attached email).

Bob Gump, BS, CMAR
Interdisciplinary Scientist/Biologist
FDA/OC/OCS/OCET

O: 301-796-0205

C: (b)(6)

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>

Sent: Saturday, March 28, 2020 12:36 PM

To: OC OCET STAFF <OCOCETSTAFF@fda.hhs.gov>

Subject: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients

<https://www.cnn.com/2020/03/27/health/n95-respirator-rewear-coronavirus-duke-trnd/index.html>

From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 3/28/2020 9:26:11 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: choloquine/hydroxychloriquine EUA
Attachments: Final Chloroquine LOA.doc; eua chloroquine fact sheet for hcp 03-28-2020 ver 4 (002) occ.docx; eua hydroxychloroquine FS for patients 03-28-20 ver 4.docx; eua hydroxychloroquine FS for hcp FINAL03-28-2020.docx; eua chloroquine fact sheet for patients 03-28-20 ver 4 occ.docx; EUA Review Template.docx

Here are the package of documents that likely will not be ready for signature for **another 2 hours**- pieces are going up to Janet Woodcock, etc. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/28/2020 11:39:50 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: final hydroxy/Chloroquine EUA
Attachments: Final HydroxyChloroquine and ChloroquineLOA.doc; EUA Request for Chloroquine and Hydroxychloroquine ; Final HydroxyChloroquine and ChloroquineLOA.pdf

Signed – thanks for all your endless work on these!

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Saturday, March 28, 2020 11:35 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: final hydroxy/Chloroquine EUA

I've pulled out the letter to sign because this one had a lot of attachments. Attached is the entire package. Thanks!

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

Sent: 3/29/2020 8:34:08 AM
To: Pillai, Segaran [/o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5e546783d4445fa315d858e0c92d47-Segaran.Pil]
Subject: FYSA: Updated COVID19 ConOps Plan V3.0 per OODataCalls
Attachments: FDA COVID19 CONPLAN_March_2020 V3.0.docx; ConOps Validation CHECKLIST 3-10-20.xlsx

Good morning. This is the last version I have in email but is very much in draft. When I receive the clean version – I'll send to you.

Thanks,
Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/29/2020 8:37:49 AM
To: Pillai, Segaran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d5e546783d4445fa315d858e0c92d47-Segaran.Pil]
Subject: DRAFT COVID19 ConOps Plan V3.0 per OODataCalls
Attachments: FDA COVID19 CONPLAN_March_2020 V3.0.docx

Good morning. This is the last version I have in email but is very much in draft and is updated as needed. When I receive the clean version – I'll send to you. Let me know if you have any additions for consideration.

Thanks,
Denise

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/29/2020 8:53:50 AM
To: O'Shaughnessy, Jacqueline A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fcc0bbfc81941e497313b309196f28b-OSHAUGHNESS]
Subject: FW: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Attachments: Final_OHRP statement on COVID-19 draft 3-20-20 v2 clean.docx; Control Sheet - 00433636-AS-849348.docx

Importance: High

Good morning Jackie. Do you want to send to OCC or have Rakesh track and follow. Anyone else?

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:31 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
Subject: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Good morning.

The Department sent the attached document yesterday evening for FDA's r/c with a due date of Noon on March 30th.

Office for Human Research Protections
Department of Health and Human Services
OHRP Guidance on COVID-19
March 20, 2020

Please have the appropriate folks r/c and provide me with the edits/comments in Track changes.

Let me know if you have any questions/concerns.

Thank you,

Wanda

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/29/2020 11:38:43 AM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Attachments: Final_OHRP statement on COVID-19 draft 3-20-20 v2 clean.docx; Control Sheet - 00433636-AS-849348.docx

Importance: High

Hi Michael,

Please let me know if IMG is handling review and clearance of this. OGCP, OCS (Jackie), and OCC (Denise Zavagno reviewed previously). Not certain if anyone else from OP needs to see it.

Call me if anything else needed.

Thank you,
Denise

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:31 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
Subject: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Good morning.

The Department sent the attached document yesterday evening for FDA's r/c with a due date of Noon on March 30th.

Office for Human Research Protections
Department of Health and Human Services
OHRP Guidance on COVID-19
March 20, 2020

Please have the appropriate folks r/c and provide me with the edits/comments in Track changes.

Let me know if you have any questions/concerns.

Thank you,

Wanda

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 3/29/2020 7:04:27 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abdo, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dca42e5f1795433c9df447f8f11bc80e-Mark.Abdo]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
CC: Hashemi, Sema [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e1d21c497e845739552ff0a9c6c9bb1-SHashemi]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: SHORT FUSE REVIEW: USG International COVID-19 Strategy
Attachments: USG Strategy for 2019 Novel Coronavirus Response 28Mar2020 - draft 5-OGAedits.docx; USG-global package_DRAFT_03.28.20-OGAedits.docx

Importance: High

Hi. Please let me know if you have any comments/edits. Also please share w/anyone else that should review. Thx - michael

From: Fernandez, Jose (OS/OGA) <Jose.Fernandez@hhs.gov>
Sent: Sunday, March 29, 2020 5:35 PM
To: Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Higgs, Elizabeth S (NIH) <ehiggs@niaid.nih.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Moudy, Robin (OS) <Robin.Moudy@hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>
Subject: SHORT FUSE REVIEW: USG International COVID-19 Strategy
Importance: High

Dear Colleagues,

The National Security Council (NSC) requested the development of an overarching framework for U.S. government activities implemented internationally to support countries' public health responses to the coronavirus (COVID-19) pandemic and to prioritize action to support the U.S. response to COVID-19 globally as we move forward. This strategy will guide U.S. government policy, program, and resource decisions and communicate the U.S. government international public health response to the global crisis. It outlines the U.S. government's approach to support response to the COVID-19 pandemic abroad, in support of National Security Strategy objectives to protect the American people, homeland, and way of life, preserve peace through strength, and advance American influence. The strategy calls on the expertise of multiple Executive Branch departments and agencies including the Department of State, U.S. Agency for International Development, Department of Health and Human Services, Centers for Disease Control and Prevention, Department of Defense, and others. It is nested under existing White House-level strategies including the National Security Strategy, National Biodefense Strategy, and the Global Health Security Strategy, which already define foundational objectives, roles, and responsibilities for executive branch agencies in protecting U.S. health security by mitigating the spread of infectious disease threats abroad.

Attached is the latest version of the strategy (*U.S. Government Action Plan to Support Partner Countries in Responding to COVID-19*) that includes edits OGA, along with a shorter external talking points document. Departments and agencies have been asked by NSC to obtain clearance of the attached documents by 10:00 am Monday March 30. OGA has

agreed to compile for HHS, so please provide me with your consolidated agency edits **NLT 9:00am Monday March 30**.
Our apologies in advance for the fast turnaround.

Thank you.

Jose

Jose A. Fernandez, Ph.D.

Deputy Director, Office of Pandemics and Emerging Threats

Switzer Building – Office 2305

Office of Global Affairs

U.S. Department of Health and Human Services

Phone: 202-260-6820 (desk); 202-657-2048 (mobile)

www.globalhealth.gov

From: Less, Joanne [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7AC05E5678EE49B9BAA16436B66D1E82-JRL]
Sent: 3/29/2020 8:29:48 PM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; O'Shaughnessy, Jacqueline A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fcc0bbfc81941e497313b309196f28b-OSHAUGHNESS]
CC: Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]; Zavagno, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18ed60daba0346b5b8f6277ecdb5bcb4-DZavagno]
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Attachments: Final_OHRP statement on COVID-19 draft 3-20-20 v2 clean.docx

Sorry! I spoke too soon. FDA updated its Clinical Trials COVID-19 guidance, so I added a minor edit to the last page of OHRP's document to include that.

Thanks!

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Sunday, March 29, 2020 8:25 PM
To: Less, Joanne <Joanne.Less@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Thank you.

Wanda

From: Less, Joanne <Joanne.Less@fda.hhs.gov>
Sent: Sunday, March 29, 2020 8:19 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Cc: Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Hi, Denise,

I do not have any additional comments on this document. We shared comments with OHRP on March 18th, and they have addressed those concerns.

Thank you,

Joanne

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:53 PM
To: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>

Cc: Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>
Subject: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Hi Jackie and Joanne,

If you haven't received already, please see the attached document for review and comment.

Thank you,

Best,

Denise

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:31 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
Subject: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Good morning.

The Department sent the attached document yesterday evening for FDA's r/c with a due date of Noon on March 30th.

Office for Human Research Protections
Department of Health and Human Services
OHRP Guidance on COVID-19
March 20, 2020

Please have the appropriate folks r/c and provide me with the edits/comments in Track changes.

Let me know if you have any questions/concerns.

Thank you,

Wanda

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/29/2020 9:22:42 PM
To: Sean R. Stevens [sean.stevens@hilineeng.com]; CDRH-NonDiagnosticEUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b31298151e33457eae63d331b684e15c-CDRH-NonDia]
BCC: CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]
Subject: RE: HELP: HiLine UVC Sterilization Device

Good evening Mr. Stevens,

Thank you for your email. I have included the email of the CDRH team to contact you for guidance in follow up to the information you presented below.

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-4880

From: Sean R. Stevens <sean.stevens@hilineeng.com>
Sent: Sunday, March 29, 2020 7:53 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: HELP: HiLine UVC Sterilization Device

Dear RADM Hinton,

(b)(4)

(b)(4)

(b)(4)

Thanks,

Sean Stevens, P.E.

HiLine Engineering & Fabrication, Inc.

2105 Aviator Dr. Richland WA, 99354

sean.stevens@hilineeng.com

509-420-7002 Desk

(b)(6)

Cell

This email was scanned by Bitdefender

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/30/2020 8:11:29 AM
To: Raghuwanshi, Rakesh [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Rakesh.Raghuwanshi]
Subject: FW: COVID-19 Morning CDC Update, 30 Mar 2020
Attachments: image002.png; daily_report.2020.03.30.pdf

UNCLASSIFIED // FOR OFFICIAL USE ONLY

From: Zavagno, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=18ED60DABA0346B5B8F6277ECDB5BCB4-DZAVAGNO]
Sent: 3/30/2020 9:18:38 AM
To: Russ, Wanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2900752acf81445785fb0f5b23c728c8-WRuss]; Less, Joanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7ac05e5678ee49b9baa16436b66d1e82-JRL]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; O'Shaughnessy, Jacqueline A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fcc0bbfc81941e497313b309196f28b-OSHAUGHNESS]; Davies, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6de10a7549a24a0eba052b9db5134ad6-Claire.Davi]
CC: Robb, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b6e9f29718844a138ad798a2f0698423-ROBBM]
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Attachments: Final_OHRP statement on COVID-19 draft 3-20-20 v2 clean - CBD.docx

Good morning,
Attached you will find comments from OCC. I have included Claire Davies who reviewed for legal issues involving devices.

Going forward, and in order to ensure proper tracking, please forward any COVID related documents for OCC's review to OCC's COVID inbox: (b)(5)@fda.hhs.gov.

Kind regards,
Denise Zavagno
Senior Counsel

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Monday, March 30, 2020 8:51 AM
To: Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Thank you Denise.

From: Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>
Sent: Monday, March 30, 2020 8:37 AM
To: Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

OCC is still reviewing.
We will be getting back to you shortly.
Thanks,
Denise Zavagno

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Monday, March 30, 2020 5:46 AM

To: Less, Joanne <Joanne.Less@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>

Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>

Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Importance: High

Good morning.

Please confirm that this is the only comment FDA has, or are we waiting input from others.

Thank you,

Wanda

From: Less, Joanne <Joanne.Less@fda.hhs.gov>

Sent: Sunday, March 29, 2020 8:30 PM

To: Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>

Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>

Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Sorry! I spoke too soon. FDA updated its Clinical Trials COVID-19 guidance, so I added a minor edit to the last page of OHRP's document to include that.

Thanks!

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>

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To: Less, Joanne <Joanne.Less@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>

Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>

Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Thank you.

Wanda

From: Less, Joanne <Joanne.Less@fda.hhs.gov>

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To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>

Cc: Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>

Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon

Hi, Denise,

I do not have any additional comments on this document. We shared comments with OHRP on March 18th, and they have addressed those concerns.

Thank you,

Joanne

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:53 PM
To: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>
Cc: Russ, Wanda <Wanda.Russ@fda.hhs.gov>; Robb, Melissa <Melissa.Robb@fda.hhs.gov>
Subject: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Hi Jackie and Joanne,

If you haven't received already, please see the attached document for review and comment.

Thank you,

Best,

Denise

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:31 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
Subject: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Good morning.

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Office for Human Research Protections
Department of Health and Human Services
OHRP Guidance on COVID-19
March 20, 2020

Please have the appropriate folks r/c and provide me with the edits/comments in Track changes.

Let me know if you have any questions/concerns.

Thank you,

Wanda

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/30/2020 11:14:36 AM
To: McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: FW: revised battelle eua
Attachments: Battelle EUA - 03.29.2020 - 615pm rev - clean.docx; HCP - Fact Sheet - Battelle Face Masks - 03.29.2020 - 615pm.docx; Instructions for Healthcare Facilities - 03.29.2020 - 615pm revision.docx; Instructions for Healthcare Personnel - 03.29.2020 - 615pm revision.docx; Battelle EUA - 03.29.2020 -final_dmh.pdf

From: Hinton, Denise
Sent: Sunday, March 29, 2020 7:20 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: revised battelle eua

Signed – thank you!

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Sunday, March 29, 2020 7:03 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: revised battelle eua

Attached is the revised Battelle EUA. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 3/30/2020 5:00:11 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
CC: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]
Subject: RE: EUA Products Assignment
Attachments: 20200320 COVID19 EUAs.docx

Yes. sorry

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, March 30, 2020 4:59 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: RE: EUA Products Assignment

Did you intend to send an attachment? Thanks.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 30, 2020 4:56 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Subject: EUA Products Assignment

Hello all: looping everyone into one email for awareness. I am developing a very high level document of products we have authorized, sponsors and what they do for external stakeholders. I have worked on a high level introduction and the non-diagnostic products. I also included some resources but again, very high level as to not overwhelm.

Toby and Elizabeth are helping on diagnostics. (the version they are working on is separate) – how is it going?

Who from CDER should be reviewing this? Rosemary Roberts?

OCET can you please review this in the mean time? I would appreciate assistance on sharepoint as my computer has basically been treating me like I don't actually work at FDA or it has a terrible case of COVID19.

Thank you!

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/30/2020 6:56:12 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: FW: Qiagen EUA
Attachments: 2-EUA200075 Qiagen Multiplex EUA LOA_03302020_CD (002).doc; 3-EUA200075 Qiagen Multiplex HCP FS_CD.docx; 4-EUA200075 Qiagen Multiplex Patient FS_CD (002).docx; 5-EUA 200075 QIAstat-Dx Respiratory SARS-CoV-2 Panel_IFU.docx; 2-EUA200075 Qiagen Multiplex EUA LOA_03302020_CD (002).doc; 2-EUA200075 Qiagen Multiplex EUA LOA_03302020_CD (002) (003).pdf

Thanks!

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, March 30, 2020 6:07 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Qiagen EUA

First EUA of 2 to sign for the night. This is a multiplex EUA. A bit different, but looks good. Thanks!

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/30/2020 7:11:00 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: 2d EUA for the night- NeuMoDx
Attachments: 2-EUA200073 NeuMoDx EUA LOA-03302020.doc; 3-EUA200073 NeuMoDx HCP FS 03302020.docx; 4-EUA200073 NeuMoDx Patient FS 03302020.docx; 5-EUA200073-NeuMoDx-IFU-FINAL03302020.docx; 2-EUA200073 NeuMoDx EUA LOA-03302020.pdf

Thanks Liz – much appreciated.

Best,
Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, March 30, 2020 6:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: 2d EUA for the night- NeuMoDx

NeuMoDx ready for signing. This one was a straight-forward one- high and moderate complexity labs.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/31/2020 8:57:36 AM
To: Araojo, Richardae [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0474cf3e9aea4e32980ca8f3b4ad2c1e-ARAOJOR]
Subject: FW: FDA 2019-nCoV SITREP - 30 March 2020
Attachments: 51_2019-nCoV Outbreak_FDA SITREP_30 March 2020.docx; COVID-19 Vitals_30 March 2020.docx

DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTIAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications

- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target this week
- Potential EUA for vaporized hydrogen peroxide, so hospitals may be able to re-sterilize N95s, possibly up to 20 times target ~mid-week

Medical Product Development & Availability

DIAGNOSTICS

- Pre-EUAs: 249 [+14]
- LDTs: 112 [+2] LDT firms have indicated that they have completed validation and will initiate testing^[1]
- EUAs:
 - Submissions: 88 [+9] (2 withdrawn (b)(4); no data)
 - Amendments: 12 [+2] requests, 5 have been granted; 2 required re-issue of the original EUA
 - Issued: 22 [+2] (22 [+2] molecular; 0 serological)
- Manufacturer Test Notifications^[2]: 34 [+7] firms have notified us, 30 [+7] serology and 4 PCR.

PPE: Authorized an amendment to Battelle's EUA allowing them to operate their decon system at multiple locations

VENTILATORS: Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

NEW DEVICE GUIDANCES

- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

HUMAN DRUGS: 26 [+2] pre-IND, 8 IND, 0 [-1] Pre-EUA, 1 [-1] EUA request; 1 EUA issued (chloroquine/hydroxychloroquine)

- Remdesivir: 574 EIND requests authorized to date; ACTT trial - 253 (+31) patients enrolled (440 target) at 37 sites
- HAND SANITIZER:** CDER/OMQ has been contacting manufacturers that are large producers of hand sanitizer (b)(4) can manufacture a large quantity of hand sanitizer and will partner with the Red Cross (b)(4) are also interested and will consult with OMQ when the API ethanol guidance is released.

BIOLOGICS: 17 [+1] pre-IND, and 1 IND

(b)(4)

Inspections

- **ORA Inspections:** ORA continues to accomplish inspections that are deemed Mission Critical and ORA IMG Reps continue to triage local field inquiries from states, industry, and other agencies into IMG through RFI process.

^[1] EUA submissions should be submitted within 15 working days of FDA notification

^[2] Resulting from the new Regulatory relief policy update

OUTREACH TO PRODUCT MANUFACTURERS

Product
Biologics
Human Drugs
N95s
Surgical Masks
Surgical Gowns
Surgical Isolation Gowns
Gloves
Surgical accessories and non-surgical isolation gowns
Infrared Thermometers
Ventilators
Vent support devices
Essential Devices - INTL ^[4]
Animal Drugs

(b)(5)

Fraudulent Products

- Warning Letters: **12 [+3]** issued; **40** pending
- 3 issued today: (1) Halosense Inc., (2) JRB Enterprise Group Inc. DBA Anti-Aging Bed, and (3) FullerLifeC60 LLC

Food Safety

- Nothing to report

Legislative Activities

- **Briefings/Hearings Today:** N/A
- **Upcoming Briefings/Hearings:** N/A

Communications

- **Released today:**
 - **Press statements** - Coronavirus (COVID-19) Updates:
 - FDA expedites review of diagnostic tests to combat COVID-19
 - FDA on Signing of the COVID-19 Emergency Relief Bill, Including Landmark Over-the-Counter Drug Reform and User Fee Legislation
 - **Stakeholders**

^[3] Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

^[4] China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain

- Cross-cutting: Updated guidance, Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, with an appendix adding questions and answers
- CDRH: Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency
- Listserv messages/social media on QAs for clinical trials during COV19 (updated guidance to add QAs)

Operations

- PHS Deployments: **169 (+8)** officers are deployed; **57 (-9)** officers are rostered to deploy

Requests for Information (RFIs)^[5]

- Total Received: **125 (+10)**
- Total Pending: **22 [18%]**
- Total Resolved: **103 (+5) [82%]**

External Situation Reports

- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 30, 2020

^[5] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/30/2020

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 3/31/2020 9:04:15 AM
To: 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: JIC 9:30 notes
Attachments: 20200331_JICMeetingNotes.docx

JIC daily check-in M-F, 9:30 – 10:30 a.m. **WebEx only.** For first ~30 minutes, we will run down status of current items. 10:00-10:30, will focus on forward look/strategy or topic of the day. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

Reminders:

- Please put all documents for JIC/IMG & OCC review in the IMG/JIC SharePoint, and route with a SP link (not as file attachment)
 - This is on request of IMG leadership for version control, and to cut down on # of emails
 - Put text for review below the SP link in your email, so people can easily determine if they need to review or FW
 - Process reference docs
 - JIC overview w/more info on process, routing, etc. (March 23 slides)
 - Add the JIC clearance table at the bottom of your docs
- **All COVID-19-related tweets from FDA official accounts need to be cleared by JIC (including OCC) before posting.** To expedite this, please send draft tweets in batches, where possible, to:
2019nCoVFDAIMGJICSocial@fda.hhs.gov

TODAY'S FOCUS DISCUSSION (Second half of meeting)

- Hot topics for the group?
- Strategy / forward look

COMMS PIPELINE– for each item below, chime in on plans for:

- ✓ Press
- ✓ Social
- ✓ Other external comms (e.g., consumer, Voices)
- ✓ Stakeholder
- ✓ Web
- ✓ Internal

Standing item:

- What is Dr. Hahn up to today? (press, media, etc. – need for various report-outs)
- On-camera interview w/One America News Network today
- Press briefing today at WH ~ 5 pm

Released today, March 31

- Press statements – Coronavirus (COVID-19) Updates:
- Daily Roundup March 31, 2020 - Includes information about ...

- ...
- Web pages:
- ...
- EUAs:
- ...
- Stakeholders
- ...

Likely today, March 31

- Web updates:
 - CTP statement on court filing/pushing back May 12 deadline
 - CVM: Web landing page for veterinary and animal food and drug guidance
 - CDRH: New web page / updates to existing page: FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data (target March 31)
 - CDRH: EUAs coming soon: Co-Diagnostics
 - Update CVM FAQs - Animal Food & COVID-19
- Stakeholders:
 - CDRH: Update to masks and respirators guidance, expected March 31
-

Likely tomorrow, April 1

- Press statements - Coronavirus (COVID-19) Updates:
 - Daily roundup April 1, 2020
 - Blood donor guidance (target April 1) w/potential media telebriefing
 -
 -
- Media Briefing: FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19 (April 1, 10:15 a.m.)
 - Web updates:
 - CDRH:
 - Device shortages web page (target April 1)
 - Letter to HCPs on eye protection, and head and shoe covers (target April 1)
 - Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
 - Stakeholders:
 - CDRH: Thermometers policy, expected April 1
 - Consumer & patient updates:
 - Stakeholder comms for patients/HCPs w/a variety of chronic conditions (target March 31/April 1)
 -

Released yesterday, March 30

- Press statements – Coronavirus (COVID-19) Updates:
 - Daily Roundup March 30, 2020 - Includes information about EUAs, and enforcement policies to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers, and expand the availability of gowns and other protective apparel
 - FDA expedites review of diagnostic tests to combat COVID-19
 - FDA on Signing of the COVID-19 Emergency Relief Bill, Including Landmark Over-the-Counter Drug Reform and User Fee Legislation
- OpEd CNN: What we at the FDA are doing to fight Covid-19 (Hahn)
- Web pages:
 - CDRH new and updated FAQs on Diagnostic Testing for SARS-CoV-2.

- EUAs:
 - Two New Diagnostic EUAs posted (Qiagen, NeuMoDx) + CDC amendment
- Stakeholders
 - Cross-cutting: Updated guidance, Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, with an appendix adding questions and answers
 - CDRH: Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency
 - Listserv messages/social media on QAs for clinical trials during COV19 (updated guidance to add QAs)
 - CDER: Updated Master List of Reactive Q&As for Hand Sanitizer Guidances
 - CDER: Email to Trade Press Constituents Re: CDER Staff email about Over-the-Counter Monograph User Fee Act Signed Into Law
- Internal USG: Provided Coronavirus Treatment Acceleration Program (CTAP) one-pager for White House, and TPs to inform POTUS remarks

Pending release, March 31-April 4 [all internal confidential]

- Press statements - Coronavirus (COVID-19) Updates:
 - Daily roundups
 - FDA Continues to Accelerate Development of Novel Therapies for COVID-19 (new timing: target this week)
- CDRH:
 - Webinar on EUAs for ventilators and ventilator support accessories (target TBD)

(b)(4)

- Other EUAs coming soon: ...
 - Upcoming IIE Guidances:
 - Infusion Pumps policy, expected April 2
- CDER:
 - Guidance on PPE for pharmacy compounding (target TBD)
- CBER:
 - Updated web posting to HCT/P establishments on COVID-19
- Press statements:
 - Convalescent plasma w/ info on Red Cross role (target April 2 or 3) + stakeholder messages
- CFSAN:
 - Foods media telebriefing: may happen later this week, a good evergreen media piece we can do at any time
- CVM:
 - FAQs for main FDA COVID-19 page regarding pets and coronavirus
- ORA:
 - ...
- Consumer & patient updates:

(b)(5)

- New weekly CU featuring new additions to COVID-19 Q&A page
- Web updates
 - FDA Voices: PHS role in response
 - COVID-19 medical countermeasures (cross-cutting, including regulatory science) (target April 3)
 - New web page Coronavirus Treatment Acceleration Program (CTAP), in conjunction with press release
 - ...
- Stakeholder:
 - Planning additional stakeholder calls, similar to successful March 28 CMS call with Drs. Hahn, Shah and other FDA experts

Routine/daily/weekly activities:

- Daily - Prepared talking points for Commissioner Hahn for daily White House Task Force and press briefing
- Daily - Prepared/posted tweets/graphics on above topics for Commissioner and FDA accounts
- 2x/ weekly (Wed & Fri): COVID-19 response recap emails to stakeholders
- Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- White House press conference/TF
- NICCL calls (daily 10:15 a.m.)
- Latest AEG discussions

Pending, from previous discussions

- FDA outreach to diverse populations (Gloria Sanchez-Contreras, OMA)
- CVS's request for national guidance on recommended prescription limits for certain drugs (proactive FDA messaging / what we are doing w/stakeholders on this)
- OMA working on a PR

MEDIA MONITORING

- See NICCL JIC social listening reports + other files in NICCL JIC folder

Reviews

Note: This table includes mostly items still in JIC/IMG review, to help JIC/IMG members easily keep track of outstanding reviews. It is NOT a comprehensive list of all pending comms. (Short turnaround reviews that happen after ~4 p.m. with deadlines before ~9 a.m. the following day are not included.)

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Center(s) Responsible	Notes
White House TPs (folder – new location)	Daily by 12 pm (time may vary)	Stephanie Caccamo/ Carly McWilliams		All	Note: These do evolve and shift throughout the day as we are asked to add additional content.
Daily round-up press statement <u>March 31</u>	3:00 p.m. daily	Brittney Manchester		All	Add your own plain language bullets about your center's comms of the day – new process
<u>MCMi weekly stakeholder email</u>	<u>March 31, noon</u>	April Finnen	JIC/IMG	OCET	Recap of cleared materials + 3D printing tweet thread

Comm	Clearance Due	Contact (JIC)	Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)	Center(s) Responsible	Notes
<u>PREDICT Question from Oversight</u>	April 2 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
<u>House O&R Letter to AMA and CDC regarding Testing</u>	April 3 12 PM	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Rep. Roy PPE inspections letter</u>	April 10 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDRH	
<u>Rep. Quigley (multi member) letter re blood donations</u>	April 10 COB	Caitlin Pennington/ Matthew Locke	JIC/IMG	CDER	
FUTURE COMMS					
Daily tweets (including evergreen + weekends)	Daily before 3:00 p.m.	Abby Capobianco / Erin Ruberry		All	Ongoing: time-sensitive Commissioner tweets need to be AEG-cleared before 3:00 p.m. daily
WORKING COPY of the TPs	Daily by 3 p.m. JIC input	Alex Wohl	JIC/IMG	All	

April Finnen

IMG JIC Lead

2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)

U.S. Food and Drug Administration

Desk: 240-402-0470

EOC: 301-796-8281 (hours at EOC: Mon. & Thurs. 9:00 a.m. – 11:30 a.m., 1:00 – 3:00 p.m.)

Cell: (b)(6) ← Call this # or IM/Skype to reach me

Email: april.finnen@fda.hhs.gov

JIC (Joint Information Center) email: 2019-nCoVFDAIMGJIC@fda.hhs.gov



From: Slikker, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117DE5CB256B4ABA9F0126E8423D09E5-WSLIKKER]
Sent: 3/31/2020 9:44:42 AM
To: Schnackenberg, Bradley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01c401585aa44f1ca109a5e7b201939c-BSchnackeb]; Mendrick, Donna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4a2be78d4cfe4c8fa2685b38cbdd6e25-DMendrick]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]; Nayak, Rajesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f8a765c4c21b441a936fa746058a83e4-Rnayak]; Ashcraft, Charlotte [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3defaed236074242aced487d77b09b47-Cmashcraft]; Cason, Winona [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3434073fc4cc4b578c59ca60a5da91f8-Winona.Caso]; Vyas, Tonya J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2470693cf04a4b08ac91afa828f7e187-TVyas]; Robinson, Moses [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e714cf6f557c41a498288ee221e4d532-MRobinson]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Azevedo, Marli [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=48e5c1830c67405d9f47a4260af1ccad-MAzevedo]
CC: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]
Subject: FW: Mini review on prospects for COVID-19 vaccines
Attachments: Vaccines-for-COVID-19-Perspectives-Prospects-and-Challenges-Based-on-Candidate-SARS-MERS-and-Animal-Coronavirus-Vaccines.pdf

Thank you Marli---

I am sharing this review with others---Bill

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>

Sent: Tuesday, March 31, 2020 8:30 AM

This minireview was written by my former mentor. She has worked with coronaviruses for more than 50 years and is a member of the National Academia of Science.

From: Slikker, William [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=117DE5CB256B4ABA9F0126E8423D09E5-WSLIKKER]
Sent: 3/31/2020 9:52:56 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: FYSA: FDA 2019-nCOV SITREP - 30 March 2020

Thank you Denise---Bill

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 8:01 AM
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>
Subject: FYSA: FDA 2019-nCOV SITREP - 30 March 2020

DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTIAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications

- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target this week
- Potential EUA for vaporized hydrogen peroxide, so hospitals may be able to re-sterilize N95s, possibly up to 20 times target ~mid-week

Medical Product Development & Availability

DIAGNOSTICS

- Pre-EUAs: **249 [+14]**
- LDTs: **112 [+2]** LDT firms have indicated that they have completed validation and will initiate testing^[1]
- EUAs:
 - Submissions: **88 [+9]** (2 withdrawn (b)(4) no data)
 - Amendments: **12 [+2]** requests, **5** have been granted; **2** required re-issue of the original EUA
 - Issued: **22 [+2]** (**22 [+2]** molecular; **0** serological)
- Manufacturer Test **Notifications**^[2]: **34 [+7]** firms have notified us, **30 [+7]** serology and **4** PCR.

PPE: Authorized an amendment to Battelle's EUA allowing them to operate their decon system at multiple locations

VENTILATORS: Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

NEW DEVICE GUIDANCES

- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

HUMAN DRUGS: **26 [+2]** pre-IND, **8** IND, **0 [-1]** Pre-EUA, **1 [-1]** EUA request; **1** EUA issued (chloroquine/hydroxychloroquine)

- Remdesivir: 574 EIN requests authorized to date; ACTT trial - **253 (+31)** patients enrolled (440 target at 37 sites)

HAND SANITIZER: CDER/OMQ has been contacting manufacturers that are large producers of hand sanitizers; (b)(4) can manufacture a large quantity of hand sanitizer and will partner with the Red Cross. (b)(4) are also interested and will consult with OMQ when the API ethanol guidance is released.

^[1] EUA submissions should be submitted within 15 working days of FDA notification

^[2] Resulting from the new Regulatory relief policy update

(b)(4)

Inspections

- **ORA Inspections:** ORA continues to accomplish inspections that are deemed Mission Critical and ORA IMG Reps continue to triage local field inquiries from states, industry, and other agencies into IMG through RFI process.

Medical Product Supply Chain^[3]

OUTREACH TO PRODUCT MANUFACTURERS			
Product	# Contacted	# Responded	Assessment as of 03/25
Biologics			(b)(5)
Human Drugs			
N95s			
Surgical Masks			
Surgical Gowns			
Surgical Isolation Gowns			
Gloves			
Surgical accessories and non-surgical isolation gowns			
Infrared Thermometers			
Ventilators			
Vent support device			
Essential Devices - INTL ^[4]			
Animal Drugs			

Fraudulent Products

- Warning Letters: 12 [+3] issued; 40 pending
- 3 issued today: (1) Halosense Inc., (2) JRB Enterprise Group Inc. DBA Anti-Aging Bed, and (3) FullerLifeC60 LLC

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- **Briefings/Hearings Today:** N/A
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^[3] Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

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-
-
-
-
-
-

^[5] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/30/2020

From: Pillai, Segaran [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1D5E546783D4445FA315D858E0C92D47-SEGARAN.PIL]
Sent: 3/31/2020 3:22:51 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Attachments: COVID 19_Fact Sheet_v1_03312020_244pm_final.docx

Here it is.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/31/2020 8:14:06 PM
To: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]
Subject: FDA 2019-nCoV SITREP - 31 March 2020
Attachments: COVID-19 Vitals_31 March 2020.docx; 52_2019-nCoV Outbreak_FDA SITREP_31 March 2020.docx

DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTIAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications

- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target 04/01

(b)(4) (b)(5)

- Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)
- Request from the Embassy of Pakistan to be included in the list of countries covered by the EUAs for remdesivir and Abbott's diagnostic test is being considered by CDER.

Medical Product Development & Availability

DIAGNOSTICS

- Pre-EUAs: 261 [+12]
- LDTs: 117 [+5] LDT firms have indicated that they have completed validation and will initiate testing^[1]
- EUAs:
 - Submissions: 100 [+12]
 - Amendments: 12 [+2] requests, 6 (+1) have been granted; 2 required re-issue of the original EUA
 - Issued: 23 (22 molecular; 1 [+1] blanket EUA for molecular tests; 0 serological)
- Manufacturer Test **Notifications**^[2]: 37 [+3] firms have notified us, 33 [+3] serology and 4 PCR.

PPE: CDRH is evaluating 24 non-NIOSH-approved respirator EUA requests for KN95s that indicate they have the European CE mark or the Australian Register of Therapeutic Goods Certificate of Inclusion.

VENTILATORS: CDRH authorized the addition 4 ventilator products to Appendix B of the ventilator EUA

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

HUMAN DRUGS: 32 [+6] pre-INDs, 13 [+5] INDs, 0 Pre-EUAs, 3 [+1] EUA requests^[3]; 1 EUA issued (chloroquine/hydroxychloroquine)

- Remdesivir: 589 [+15] EIND requests authorized to date; ACTT trial - 274 (+21) patients enrolled (440 target) at 37 sites

(b)(4)

- Convalescent Plasma: CBER has granted—and continues to grant—numerous EINDs for convalescent plasma

Inspections

- **ORA Inspections:**

^[1] EUA submissions should be submitted within 15 working days of FDA notification

^[2] Resulting from the new Regulatory relief policy update

^[3] 1 EUA request is for a product already available under IND

- ORA sent **20** requests for records to firms pursuant to authority under 704(a)(4) of the FD&C Act. **17** firms confirmed receipt of the request. To date, **1** site sent all records requested & **7** others submitted partial records.
- OEIO and DSS has increased our surveillance of products manufactured or shipped from firms whose inspections have been postponed.
- **CBER:** FDA/CBER continues to work to ensure cGMP compliance by seeking potential solutions when inspections and FDASIA 706 authority are not possible.
- **CDER:** Applications for albuterol MDI and lopinavir/ritonavir (a President’s Emergency Plan for AIDS Relief (PEPFAR) tentative approval resubmission) have been prioritized. An assessment of manufacturing for an albuterol MDI was acceptable. An API facility for lopinavir/ritonavir recently received a warning letter; (b)(5) _____

Medical Product Supply Chain^[4]

OUTREACH TO PRODUCT MANUFACTURERS			
Product	# Contacted	# Responded	Assessment as of 03/25
Biologics	58	52 (89%)	No negatively impacted firms, no supply chain disruptions
Human Drugs	183	170 (93%)	No major supply chain disruptions (One respondents has reported a drug shortage associated with the COVID-19 outbreak. Drug product is not medically necessary. Other oral beta-blockers can be used as alternatives.) All the pending chloroquine, hydroxychloroquine, and azithromycin ANDAs have been requested for prioritization. Albuterol MDI will be added to this list soon.
N95s	23	12 (52%)	9 firms report being adversely affected. Common concerns include insufficient raw materials, backorders, export restrictions, workforce shortages, and government nationalization of their facilities.
Surgical Masks	42	28 (67%)	14 firms report being adversely affected. Common concerns include insufficient raw materials, the manufacturer has shut down production of non-N95 masks, export is banned, and shortages of workers and raw materials.
Surgical Gowns	59	33 (65%)	14 firms report being adversely affected. Manufactures indicated they are working at lower capacity because of workforce shortages, raw material shortages, travel bans, and export issues.
Surgical Isolation Gowns	16	7 (44%)	5 firms report being adversely affected. Common concerns were that the company had closed, export restrictions, employee shortages, raw material shortages, and government restrictions.
Gloves	294	104 (35%)	12 adversely affected. Common concerns included lack of raw materials and workforce shortages. Manufactures also noted they are experiencing an increase in demand.
Surgical accessories and non-surgical isolation gowns	232	84 (36%)	25 adversely affected
Infrared Thermometers	26	20 (77%)	15 adversely affected. Overarching concerns reduction in workforce and supply shortages of critical components (e.g., sensor).
Ventilators	102	21 (21%)	3 adversely affected. Main reason given was supply chain disruptions originating in China.
Vent support devices	62	5 (8%)	2 adversely affected. Main reason given was supply chain disruptions originating in China.
Essential Devices - INTL ^[5]	340	240 [+3] (71%)	24 adversely affected. Manufacturing issues that include but not limited to workforce availability, transportation delays, and longer lead times with suppliers.
Animal Drugs	94	87 [+1] (93%)	7 adversely affected

Fraudulent Products

- Warning Letters: **13 (+1) issued; 44 pending**
- 1 issued today to Neuro XPF for a CBD product.

Food Safety

- **CFSAN released two guidance documents:**
- FDA Provides Flexibility Regarding Labeling Requirements for Menus During the COVID-19 Pandemic

[4] Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

[5] China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain

- Guidance for Industry: Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency

Legislative Activities

- **Briefings/Hearings Today:** N/A
- **Upcoming Briefings/Hearings:**
 - 4/2, 2:00PM: FEMA Region III Bicameral Hill member and staff briefing; FDA briefer is TBD.
 - 4/3, 2:00PM: Bicameral Hill member and staff briefing; FDA will be available for Q&A; Dr. Shah will represent FDA.

Communications

- **Released today:**
 - Press statements – FDA Continues to Accelerate Development of Novel Therapies for COVID-19
 - Web updates:
 - CTP: FDA Submits Request to Court to Extend Premarket Application Deadline for Certain Deemed Products
 - CDER: Coronavirus Treatment Acceleration Program (CTAP)
 - CFSAN is now linking from agency [FAQ page](#) to a *For Consumers* drop down on the CFSAN COVID-19 [FAQ page](#)
 - Added *What's New* section on CFSAN COVID-19 [FAQ page](#) to highlight new info.
 - CVM: CVM landing page for COVID-19
 - CVM: Industry FAQs: Animal Food Safety and the Coronavirus Disease 2019 (COVID-19)

Operations

- PHS Deployments: **150 (-19)** officers are deployed; **82 (+25)** officers are rostered to deploy

Requests for Information (RFIs)^[6]

- Total Received: **141 (+16)**
- Total Pending: **24 [17%]**
- Total Resolved: **117 (+14) [83%]**

External Situation Reports

- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 30, 2020
- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 31, 2020

^[6] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/31/2020

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/31/2020 9:25:13 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: Request re:COVID19 Fact Sheet
Attachments: COVID 19_Fact Sheet_v1_03312020_244pm_final.docx

Hi Michael and April,

Pillai (OLS) drafted the attached COVID19 FACT Sheet - please determine how best to share present – webpage/SitRep?

Thank you,

Denise

From: Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
Sent: Tuesday, March 31, 2020 3:57 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject:

Please use this version. I had to fixed a spelling error.
Pillai

From: Araojo, Richardae [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0474CF3E9AEA4E32980CA8F3B4AD2C1E-ARAOJOR]
Sent: 3/31/2020 9:50:37 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Re: FDA 2019-nCOV SITREP - 31 March 2020

Thanks

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 31, 2020 at 8:14:28 PM EDT
To: Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>
Subject: FDA 2019-nCOV SITREP - 31 March 2020

FDA Response to COVID-19
SITREP #52 ; 31 March 2020



DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTIAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications

- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus [COVID-19] Diagnostic Tests (April 1)
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target 04/01

(b)(4) (b)(5)

- Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)
- Request from the Embassy of Pakistan to be included in the list of countries covered by the EUAs for remdesivir and Abbott's diagnostic test is being considered by CDER.

Medical Product Development & Availability

DIAGNOSTICS

- Pre-EUAs: **261 [+12]**
 - LDTs: **117 [+5]** LDT firms have indicated that they have completed validation and will initiate testing^[1]
 - EUAs:
 - Submissions: **100 [+12]**
 - Amendments: **12 [+2]** requests, **6 (+1)** have been granted; **2** required re-issue of the original EUA
 - Issued: **23 (22 molecular; 1 [+1] blanket EUA for molecular tests; 0 serological)**
 - Manufacturer Test **Notifications**^[2]: **37 [+3]** firms have notified us, **33 [+3]** serology and **4 PCR**.
- PPE: CDRH is evaluating 24 non-NIOSH-approved respirator EUA requests for KN95s that indicate they have the European CE mark or the Australian Register of Therapeutic Goods Certificate of Inclusion.

VENTILATORS: CDRH authorized the addition **4** ventilator products to Appendix B of the ventilator EUA

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

HUMAN DRUGS: 32 [+6] pre-INDs, 13 [+5] INDs, 0 Pre-EUAs, 3 [+1] EUA requests^[3]; 1 EUA issued (chloroquine/hydroxychloroquine)

- Remdesivir: 589 [+15] EIND requests authorized to date; ACTT trial - 274 (+21) patients enrolled (440 target) at 37 sites

(b)(4)

- Convalescent Plasma: CBER has granted—and continues to grant—numerous EINDs for convalescent plasma

Inspections

- **ORA Inspections:**

- ORA sent 20 requests for records to firms pursuant to authority under 704(a)(4) of the FD&C Act. 17 firms confirmed receipt of the request. To date, 1 site sent all records requested & 7 others submitted partial records.

- OEIO and DSS has increased our surveillance of products manufactured or shipped from firms whose inspections have been postponed.

- **CBER:** FDA/CBER continues to work to ensure cGMP compliance by seeking potential solutions when inspections and FDASIA 706 authority are not possible.

- **CDER:** Applications for albuterol MDI and lopinavir/ritonavir (a President’s Emergency Plan for AIDS Relief (PEPFAR) tentative approval resubmission) have been prioritized. An assessment of manufacturing for an albuterol MDI was acceptable. An API facility for lopinavir/ritonavir recently received a warning letter; (b)(5)

Medical Product Supply Chain^[4]

OUTREACH TO PRODUCT MANUFACTURERS			
Product	# Contacted	# Responded	Assessment as of 03/25
Biologics	58	52 (89%)	No negatively impacted firms, no supply chain disruptions
Human Drugs	183	170 (93%)	No major supply chain disruptions (One respondents has reported a drug shortage associated with the COVID-19 outbreak. Drug product is not medically necessary. Other oral beta-blockers can be used as alternatives.) All the pending chloroquine, hydroxychloroquine, and azithromycin ANDAs have been requested for prioritization. Albuterol MDI will be added to this list soon.
N95s	23	12 (52%)	9 firms report being adversely affected. Common concerns include insufficient raw materials, backorders, export restrictions, workforce shortages, and government nationalization of their facilities.
Surgical Masks	42	28 (67%)	14 firms report being adversely affected. Common concerns include insufficient raw materials, the manufacturer has shut down production of non-N95 masks, export is banned, and shortages of workers and raw materials.
Surgical Gowns	59	33 (65%)	14 firms report being adversely affected. Manufactures indicated they are working at lower capacity because of workforce shortages, raw material shortages, travel bans, and export issues.
Surgical Isolation Gowns	16	7 (44%)	5 firms report being adversely affected. Common concerns were that the company had closed, export restrictions, employee shortages, raw material shortages, and government restrictions.
Gloves	294	104 (35%)	12 adversely affected. Common concerns included lack of raw materials and workforce shortages. Manufactures also noted they are experiencing an increase in demand.
Surgical accessories and non-surgical isolation gowns	232	84 (36%)	25 adversely affected
Infrared Thermometers	26	20 (77%)	15 adversely affected. Overarching concerns reduction in workforce and supply shortages of critical components (e.g., sensor).
Ventilators	102	21 (21%)	3 adversely affected. Main reason given was supply chain disruptions originating in China.
Vent support devices	62	5 (8%)	2 adversely affected. Main reason given was supply chain disruptions originating in China.
Essential Devices - INTL ^[5]	340	240 [+3] (71%)	24 adversely affected. Manufacturing issues that include but not limited to workforce availability, transportation delays, and longer lead times with suppliers.
Animal Drugs	94	87 [+1] (93%)	7 adversely affected

Fraudulent Products

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- 1 issued today to Neuro XPF for a CBD product.

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- **CFSAN released two guidance documents:**
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- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 31, 2020

^[1] EUA submissions should be submitted within 15 working days of FDA notification

^[2] Resulting from the new Regulatory relief policy update

^[3] 1 EUA request is for a product already available under IND

^[4] Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

^[5] China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain

^[6] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/31/2020

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 4/1/2020 6:01:12 PM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]
Subject: FW: Ipsum EUA
Attachments: 2-EUA200088 Ipsum EUA LOA_04012020_CD.doc; 3-EUA200088 Ipsum HCP FS.docx; 4-EUA200088 Ipsum Patient FS.docx; 5-EUA200088 Ipsum EUA Summary 04012020.doc; 6-EUA200088 COV-19 IDx Assay SOP rev 04012020.pdf; 2-EUA200088 Ipsum EUA LOA_04012020_CD.pdf

Thank you!

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 5:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Ipsum EUA

This is another PCR test, not the serology, ready for signing. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 4/1/2020 9:13:11 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: COVID19 EUAs

Okay, I think I can do that for the diagnostics and for the non-NIOSH products I think I can just list the countries.

Jurisdiction ⁷	Performance Standard	Acceptable product classifications	Standards/ Guidance Documents	Protection Factor ≥ 10
Australia	AS/NZS 1716:2012	P3, P2	AS/NZS 1715:2009	YES
Brazil	ABNT/NBR 13698:2011	PFF3, PFF2	Fundacentro CDU 614.894	YES
Europe	EN 149-2001	FFP3, FFP2	EN 529:2005	YES
Japan	JMHLW-2000	DS/DL3 DS/DL2	JIS T8150: 2006	YES
Korea	KMOEL-2017-64	Special 1st	KOSHA GUIDE H-82-2015	YES
Mexico	NOM-116-2009	N100, P100, R100, N99, P99, R99, N95, P95, R95	NOM-116	YES

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 9:04 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: COVID19 EUAs

I think you could just do bullets under the EUA in the second column.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 8:45 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: COVID19 EUAs

Okay, I will work on figuring out a way to integrate the list of everything under the EUAs.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 8:43 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: COVID19 EUAs

For the umbrella EUAs we need to list every product that has been approved under it and keep updating. From my perspective I think it needs to be one-stop-shopping, not to have to click on a link. Same for PPE and ventilators.

Format looks great and very user friendly.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 5:15 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: COVID19 EUAs

McWilliams, Carly has shared a OneDrive for Business file with you. To view it, click the link below.

 20200401 COVID19 EUAs.docx

Keagan and Stacy, I just got this through occ—I have inserted the latest actions (That we haven't posted/authorized yet) so it should be completely up to date tomorrow. Can you both look to make sure this hits the mark?

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 4/1/2020 9:43:37 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: Cellex EUA
Attachments: 2-EUA200058 Letter of Authorization .doc; 5-EUA200058 qSARS-CoV-2 Rapid Test Package Insert.FINAL.docx; 4-EUA200058 Patient Fact Sheet (002)_CD.docx; 2-EUA200058 Letter of Authorization_.pdf

Thanks for sending in advance Liz.

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 9:28 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Cellex EUA

I'm sending to you the Cellex letter for signing. This is the first serological test. We are still working on the HCP fact sheet. It will be done in 10 minutes, and I'll forward so you will have had the whole package. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

Sent: 4/4/2020 3:55:48 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]
CC: Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: RE: Flagging: Serology test statement, to post today

Thanks I d

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, April 4, 2020 3:49 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: Flagging: Serology test statement, to post today

Sending to him now!

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Dept. of Health and Human Services
Desk: 301-241-1056
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, April 4, 2020 3:49 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: Flagging: Serology test statement, to post today

Thx, did Anand review?

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, April 4, 2020 11:21 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>

Subject: Flagging: Serology test statement, to post today

Hi! Attached and copied below—statement explaining serology tests, our policy and clarifying the high-complexity lab and teasing forthcoming NCI efforts to validate. if you'd like to provide comment, please let me know in next few hours. I'm continuing clearance to HHS/VP, but can reconcile edits. Will send to Dr. Hahn in a bit as well.

(b)(5)

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.345.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 4/7/2020 11:58:44 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: FOR REVIEW; (b)(3) 42 USC 247d-6b(d) , (b)(5)
Attachments: (b)(3) 42 USC 247d-6b(d) , (b)(5)

Hi Denise—I can send this to the CDER leadership team on these products if helpful.

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Sent: Tuesday, April 07, 2020 11:48 AM
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>; Strom, John (OS) <John.Strom@hhs.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Ethier, Kathleen A (CDC) <kbe0@cdc.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Collins, Francis S (NIH) <collinsf@od.nih.gov>; Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>; Bright, Rick (OS) <Rick.Bright@hhs.gov>; Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>; Lambert, Linda (OS) <Linda.Lambert@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>; Meredith.L.Austin@usbordencg.mil; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Blatner@hhs.gov; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>; DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Subject: FOR REVIEW; (b)(3) 42 USC 247d-6b(d) , (b)(5)

Dear Disaster Leadership Group Members and Colleagues:

Thank you for your participation in COVID-19 Disaster Leadership Group (DLG) Meetings; (b)(3) 42 USC 247d-6b(d) , (b)(5)

(b)(3) 42 USC 247d-6b(d) , (b)(5)



(b)(3) 42 USC 247d-6b(d) , (b)(5)

We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message. Please address any questions related to this request to the DLGDESK Resource Mailbox at DLGDESK@hhs.gov.

Respectfully,

Dan

Daniel Dodgen, Ph.D.

Senior Advisor

Office of the Assistant Secretary for Preparedness and Response (ASPR)

Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515

o. (202) 245-0719

Daniel.Dodgen@HHS.Gov | www.phe.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 4/8/2020 5:55:21 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d) , (b)(5)

Thanks for update and I'll look for it this evening.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 4:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d) , (b)(5)

Hi – just FYI – CDER folks are tied up so won't have comments until this evening. -m

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Date: April 7, 2020 at 11:48:17 AM EDT

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Okay – swimming now

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U will find it in our ocean...

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FDA-OSJI-FOIA-2020-3541_00003820

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That's me – get your own title!

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Should I go higher?

Thinking I should go old-school and sign all of my emails 'your humble servant'

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Subject: FYSA: WHTF Materials 4/9 Internal Confidential
Attachments: 20200409 WHTF.docx; CovidVitals_08 APR 2020.docx

Background



20200409
WHTF.docx

Vitals



CovidVitals_08
APR 2020.docx

From: McWilliams, Carly [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 4/13/2020 11:05:15 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]
CC: Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguirri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: WHTF Materials 4/13 Internal Confidential
Attachments: 20200413 WHTF.docx; CovidVitals_10 APR 2020.docx

Background



20200413
WHTF.docx

Vitals



CovidVitals_10
APR 2020.docx

From: Lesane, Carmila [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2C76107E660E4D1ABAC3576BBC28ECAD-CARMILA.LES]
Sent: 4/13/2020 2:22:07 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Attachments: 2001767.pdf

Hi Denise,

I am sending this to you as an FYI.

Thank You!

Carmila Lesane
Correspondence Analyst
Office Of Executive Secretariat
301-796-8980



From: Johanson, Elaine [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=636A76A574AB4D4498438B47493217BC-JOHANSONE]
Sent: 4/13/2020 2:25:29 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: FW: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

(b)(6)

Larry's friend

(b)(6)

(b)(5), (b)(6)

Thanks for calling him at 3:30.

(b)(6)

(b)(5), (b)(6)

Elaine

Elaine Johanson

Director, Office of Health Informatics (Acting)

Office of the Chief Scientist
Office of Health Informatics
U.S. Food and Drug Administration
Tel: 301-796-7315
elaine.johanson@fda.hhs.gov



From: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>

Sent: Monday, April 13, 2020 2:07 PM

To: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>

Cc: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Weichold, Frank <Frank.Weichold@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Peryea, Tyler <Tyler.Peryea@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>

Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

The data use agreement, that I provided to Frank needs to be modified and shared with the General Council at FDA.

From: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>

Sent: Monday, April 13, 2020 2:03 PM

To: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>

Cc: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Weichold, Frank <Frank.Weichold@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Peryea, Tyler <Tyler.Peryea@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>

Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

That's great then we will try to find who is communicating with AMY about obtaining payer data sets. We thought it was you. (b)(4) I think Alice will (b)(5)

(b)(5)

Is Amy the sole person responsible for this. Is there a transparent process.

It is really a once in a lifetime chance to get data sets real experts on AI to work on this as a peer-peer activity. We will have to find out who the person who communicates to AMY is there any transparency in the process on what studies to do.

From: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>

Sent: Monday, April 13, 2020 1:28 PM

To: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>

Cc: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Weichold, Frank <Frank.Weichold@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Peryea, Tyler <Tyler.Peryea@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>

Subject: FW: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Larry,

I needed to work with you (b)(5)

(b)(5)

We need approval from our leadership at FDA OC and CDER first.

I am sorry, but Gunther's opinion/theories are unimportant. I recommend not mixing internal and external email recipients in your emails.

Thanks

Mitra

From: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>

Sent: Monday, April 13, 2020 1:12 PM

To: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>; Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>

Cc: Martin, David <David.Martin@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>

Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Mitra

I am very sad to hear this. All we needed from you was to present this idea to Amy and let Amy decide, that's it. We do not need any remapped data models to do this. Gunther (b)(6)

(b)(6)

(b)(6)

No-one has tried to get rid of HL-7 V3 SPL format and his validator more than me. He informed that there was a large hydroxychloroquine study going in Brazil and Brazil may shipped a large quantity of hydroxychloroquine to the US for whatever reason don't know if that true. This is a worldwide problem and we need people from all over the world to help solve it. I believe there are treatment regimens

out there that can minimize death and placement on a respirator. I believe the Chinese, Koreans, and perhaps even Germans have discovered some things and I think we have a way to discover that as well the more we collaborate. If

(b)(5)

if you want to take over

that is fine.

(b)(5)

(b)(5)

In the Netherlands

(b)(6)

is in

a coma and he was on a hydroxychloroquine regimen I am pretty sure it did not help him but it may help others. I actually think the public health labs can prove this with data we have today. EMA and China have not approved hydroxychloroquine but they have approved FAVIPRAVIR as an antiviral and TOCLIZUMAB as agent to treat or prevent cytokine storm.

(b)(5)

(b)(5)

Again I am sorry

you feel the way you I do not believe I have screwed up many projects but please let me know which ones so perhaps I can fix them. I understand that I may be in need of a babysitter and you do not want to be it. No hard feelings. I hope to continue to my collaboration with Ana to do a swot analysis on proposed drugs. I'll contact my friend at blue cross and inform her that you will be a point of contact for her. Good luck.

Best

Larry

From: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>

Sent: Monday, April 13, 2020 12:32 PM

To: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>

Cc: Martin, David <David.Martin@fda.hhs.gov>; Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>

Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Dianne,

I am working with Dr. Abernethy on mapping COVID-19 data elements to various Common Data Models and leveraging the Common Data Model Harmonization (CDMH) infrastructure.

There is a webinar led by American Medical Informatics Association (AMIA) at 4:00 pm focusing on joint FDA/NIH COVID-19 activities. I will send you the invitation.

I am not collaborating with Larry Callahan on

(b)(5)

(b)(5)

Thanks

Mitra

From: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>

Sent: Monday, April 13, 2020 11:08 AM

To: Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>

Cc: Martin, David <David.Martin@fda.hhs.gov>; Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>; Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>

Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Dianne,

Did you contact Mitra Rocca and Larry Callahan? They are exploring (b)(5) with a group of investigators. I think it is a very worthwhile effort to explore RWE.

I've cc'ed them on this response.

Greg

From: Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>
Sent: Monday, April 13, 2020 9:40 AM
To: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>
Cc: Martin, David <David.Martin@fda.hhs.gov>
Subject: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Greg,
Apologies for the requested quick turnaround. CDER received an inquiry about the use of RWD/RWE and COVID-19. Attached is our drafted response. We appreciate CBER's input by noon today.

Thanks!
Dianne

CAPT Dianne Paraoan
Associate Director for Regulatory Affairs

Office of Medical Policy
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel 301-796-3161
dianne.paraoan@fda.hhs.gov



From: Jackson, Valerie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CBEAC5D29BA247128B43177B06D5D847-VJACKSON]
Sent: 4/27/2020 11:40:07 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Raghuwanshi, Rakesh [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbcb6049edabcb11776f265a2a-Rakesh.Ragh]
Subject: Action Optional - Follow up to phone call with Mahesh Kalva.
Attachments: 2002026.pdf; 2002026a.pdf

Good afternoon,

The following is being sent to your office for action optional. If a response is issued, please send me a copy for our records.

Regards,

Valerie

Valerie Jackson Watson
Senior Correspondence Analyst
FDA Executive Secretariat
301-796-4685
valerie.jackson@fda.hhs.gov

"TIMELESS TURTLE – STEADY, DEPENDABLE, STRONG"

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 4/29/2020 5:47:21 PM
To: Raghuwanshi, Rakesh [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=Rakesh.Raghuwanshi]
Subject: FW: for your review - OCS night notes

- Ebola PCC (Policy Coordinating Committee) meeting held today
 - updates provided about the new EVD cases in the DRC
 - received updates from CDC and USAID and brainstormed actions to support response efforts

- Two COVID-19 IVD EUAs received today from CDRH for signature
 - **Rheonix COVID-19 MDx Assay** (EUA200240) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage (BAL) fluid from individuals who are suspected of COVID-19 by their healthcare provider.
 - **LabGun COVID-19 RT-PCR Kit** EUA Request Package (EUA200430) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, or oropharyngeal, anterior nasal and mid-turbinate nasal swabs, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum, from individuals who are suspected of COVID-19 by their healthcare provider.

- COVID-19 Departmental Action Group
 - Provided updates on FDA's ongoing COVID-19 response efforts: focused on near term priorities, activities, and challenges.

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 5/3/2020 10:19:14 PM
To: Hinton, Denise (Denise.Hinton@fda.hhs.gov) [/o=FDA/ou=First Administrative Group/cn=Recipients/cn=HINTOND]
Subject: FW: FDA COVID19 CONPLAN_March_2020 V3.0.docx
Attachments: FDA COVID19 CONPLAN_March_2020 V3.0.docx

From: Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Sent: Sunday, March 29, 2020 8:46 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FDA COVID19 CONPLAN_March_2020 V3.0.docx

RADM Hinton,

This is the version that was sent to OO for review and editing (if they determined it to be necessary). We'll verify with them, and if no changes will mark this one 'Final'.

r/

Tom

From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 5/11/2020 5:45:05 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package
Attachments: 2-EUA200572 Abbott Alinity NAT EUA LOA 05112020.doc; 3-EUA200572 Abbott Alinity NAT HCP FS 05112020.docx; 4-EUA200572 Abbott Alinity NAT Patient FS 05112020.docx; 5-EUA200572 Abbott Alinity NAT IFU Comb 05112020.pdf

Attached is the Abbot Alinity test- PCR ready for signature. Thanks, Liz

From: McManus, John <John.McManus@fda.hhs.gov>
Sent: Monday, May 11, 2020 5:30 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Yes, I concur. Thanks Elizabeth

-John

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, May 11, 2020 5:27 PM
To: McManus, John <John.McManus@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Yes... to the HCP as well. I will have to work with the formatting of the HCP to accept the edits. Did you concur with those as well?

From: McManus, John <John.McManus@fda.hhs.gov>
Sent: Monday, May 11, 2020 5:20 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Hi Elizabeth,

These changes are just the comma in the IFU and the Red-lined changes in the LoA, correct? If this is the case, please accept these changes as they accurately reflect IU of the assay.

Thanks

John

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, May 11, 2020 5:14 PM

To: McManus, John <John.McManus@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

I was waiting for CDRH concurrence with the proposed edits before sending to Denise to sign. Do you want me to accept them and make a clean version?

From: McManus, John <John.McManus@fda.hhs.gov>

Sent: Monday, May 11, 2020 5:10 PM

To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beale, Jacqueline <Jacqueline.Beale@fda.hhs.gov>

Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

I will relay this change to the sponsor. Please let me know when I may send their LoA over.

Thanks!

John

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Sent: Monday, May 11, 2020 2:43 PM

To: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beale, Jacqueline <Jacqueline.Beale@fda.hhs.gov>; McManus, John <John.McManus@fda.hhs.gov>

Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Attached are minor edits to the documents. Please note the need to insert a "comma" in the IFU as well (to mirror the one inserted in the IU statement of the LOA).

I had no comments to the patient fact sheet.

Thanks!

From: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>

Sent: Monday, May 11, 2020 1:49 PM

To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beale, Jacqueline

<Jacqueline.Beale@fda.hhs.gov>; McManus, John <John.McManus@fda.hhs.gov>

Subject: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Dear Jennifer, Liz, and Claire,

Please find attached for your final review the Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package (EUA20572) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swabs, self-collected at a health care location or collected by a healthcare worker, nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare worker or bronchoalveolar lavage fluid (BAL) from patients suspected of COVID-19 by their health care provider:

- 1) EUA200572 – Abbott Molecular Inc. cover letter
- 2) EUA200572 – Letter of authorization
- 3) EUA200572 - HCP Fact Sheet
- 4) EUA200572 – Patient Fact Sheet
- 5) EUA200572 – IFU Alinity m SARS-CoV-2
- 6) EUA200572 – Lead Reviewer Memorandum

Please note, the Abbott Alinity platform is for use in high and moderate complexity labs.

Also, the IFU includes a self-collection kit (for use at a healthcare facility); however, since its use is optional with this test it is not called out specifically in the letter of authorization. Abbott can consider it “authorized” as it is included in the test IFU.

CDRH considers these documents cleared.

Thank you for your continuous collaboration and help,

Tamara

Tamara Feldblyum, M.S., Ph.D.

Branch Chief,

Viral Respiratory and STI Branch

Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health

Office of Product Evaluation and Quality

CDRH | Food and Drug Administration

White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-6195

Tamara.Feldblyum@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 5/11/2020 5:49:15 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package
Attachments: 2-EUA200572 Abbott Alinity NAT EUA LOA 05112020.doc; 3-EUA200572 Abbott Alinity NAT HCP FS 05112020.docx; 4-EUA200572 Abbott Alinity NAT Patient FS 05112020.docx; 5-EUA2000572 Abbott Alinity NAT IFU Comb 05112020.pdf; 2-EUA200572 Abbott Alinity NAT EUA LOA 05112020.pdf

Signed – thanks, Liz.

Best,
Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, May 11, 2020 5:45 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

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Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Yes, I concur. Thanks Elizabeth

-John

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CDRH considers these documents cleared.

Thank you for your continuous collaboration and help,

Tamara

Tamara Feldblyum, M.S., Ph.D.

Branch Chief,

Viral Respiratory and STI Branch

Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health

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White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Ph: (301) 796-6195

Tamara.Feldblyum@fda.hhs.gov

From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 5/11/2020 5:50:19 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
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Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
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Signed – thanks, Liz.

Best,
Denise

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To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: FW: For OCS Signature today: RE: Eko ELEFT (PEUA200768) for OCC/OCET review
Attachments: EUA200768 - Letter of Authorization - 5-11-20 FINAL.docx; EAU200768 - Patient Fact Sheet - 5-11-20 FINAL.docx; EAU200768 - HCP Fact Sheet - 5-11-20 FINAL.docx; EAU200768 - Instructions for Use - 5-11-20 FINAL.docx; EUA200768 - Letter of Authorization - 5-11-20 FINAL.pdf

Signed. Thanks, Jennifer.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, May 11, 2020 6:24 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: For OCS Signature today: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

RADM Hinton,

Please sign this letter authorizing an EUA for software (ELEFT) from Eko Devices Inc. for use as a diagnostic aid to screen for potential cardiac complications associated with COVID-19.

2 fact sheets and instructions for use are also attached.

This was cleared by CDRH today and OCC (J.Gibney).

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel: 240-402-8155
Jennifer.Ross@fda.hhs.gov



From: Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>

Sent: Monday, May 11, 2020 9:51 AM

To: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Cc: Keegan, Erin <Erin.Keegan@fda.hhs.gov>; Bertram, James <James.Bertram@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>

Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Good morning everyone,

Based on our conversation last week, we've revised the scope of the Eko ELEFT EUA. The most recent version of the documents are attached. We did not make any other changes besides the scope, which is described below.

(b)(5)

Please let us know if you have any additional questions or suggestions.

Jacquie

From: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

Sent: Thursday, May 7, 2020 12:53 PM

To: Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

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Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Okay, no worries. Let's plan for talking tomorrow. Thanks!

From: Krueger, Angela C <Angela.Krueger@fda.hhs.gov>

Sent: Thursday, May 7, 2020 12:52 PM

To: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

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Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Sure – Jennifer can't attend today, and so we planned to discuss further tomorrow, but happy to do both if helpful to chat about it today. I will forward.

Angie

From: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

Sent: Thursday, May 07, 2020 12:49 PM

To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

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Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Hi Angie,

If the 1:00 pm meeting today is still happening, could you please forward me the invite? I have a couple questions on the Eko EUA.

Thanks,
Jaycie

From: Dennis, Claire <Claire.Dennis@fda.hhs.gov>

Sent: Thursday, May 7, 2020 8:27 AM

To: Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

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Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Hi Angie,

Jaycie (copied) will be handling for OCC.

Thanks,
Claire

From: Krueger, Angela C <Angela.Krueger@fda.hhs.gov>

Sent: Wednesday, May 6, 2020 10:23 PM

To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

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Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Thanks – could we take some time at the 1 pm meeting tomorrow to discuss? We can invite the relevant team members from our side. OCC – who is assigned to this one and we can invite them as well?

Angie

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Sent: Wednesday, May 06, 2020 9:36 PM

To: Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

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Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Hi Jacqueline,

It would be helpful to discuss this EUA. How much more information is required to get to approval and how long would that take them? In other cases we have seen that when an EUA is issued, there is no incentive for continued product development, yet FDA and other stakeholders would prefer to have a fully marketed product. Also, how does the clinical management of a COVID-19 patient change as a result of using this device? Those are just some of the questions that I have without reading through everything that you sent. Liz may also have questions.

Thanks,

Jennifer

From: Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>

Sent: Wednesday, May 06, 2020 9:03 PM

To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Keegan, Erin <Erin.Keegan@fda.hhs.gov>; Bertram, James <James.Bertram@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>

Subject: Eko ELEFT (PEUA200768) for OCC/OCET review

Hello OCC and OCET,

We have attached the following documents for the Eko ELEFT EUA for review:

1. Letter of Authorization
2. Fact Sheet for HCP
3. Fact Sheet for Patients
4. Instructions for Use
5. Review Memo

(b)(5)

Please let us know if you have any questions or if it would be helpful to discuss this EUA.

Jacquie

Jacqueline Gertz, Ph.D.

Regulatory Advisor

**Office of Product Evaluation and Quality
Regulation, Policy, and Guidance Staff**

Combination Products & OHT Regulatory Support Team 2
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Tel: 240-402-9677
Jacqueline.Gertz@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.



From: Raghuwanshi, Rakesh [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=3084AEDBCB6049EDABCB11776F265A2A-RAKESH.RAGH]
Sent: 5/14/2020 1:39:30 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: OCS Check-in #9 notes
Attachments: 2020-05-14 OCS Check-in #9.pdf
Importance: High

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 5/14/2020 9:23:05 PM
To: O'Shaughnessy, Jacqueline A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fcc0bbfc81941e497313b309196f28b-OSHAUGHNESS]
Subject: RE:

Thanks. I'll check to see if I need to respond.

From: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Sent: Thursday, May 14, 2020 9:21 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE:

I didn't find anything else, other than this (with the same name):

Richard M. Fleming; Denial of Hearing;
Final Debarment Order

<https://www.govinfo.gov/content/pkg/FR-2018-09-28/pdf/2018-21210.pdf>

From: O'Shaughnessy, Jacqueline A
Sent: Thursday, May 14, 2020 6:32 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re:

No, I have not received any email like this. I will check on the CT.gov # for other details and circle back.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: May 14, 2020 at 5:39:17 PM EDT
To: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Subject: FW:

I do not believe this is a legitimate source; however, have you received these emails as well?

From: Dr. Richard M Fleming (b)(6)
Sent: Thursday, May 14, 2020 2:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Dr. Richard M Fleming (b)(6)
Subject:

Dear Ms. Denise M Hinton,

As the Chief Scientist for the FDA, who authorized the EUA for Remdesivir, I am inquiring about the actual (original) data used to support the EUA. Specifically, the NCT04280705 data.

As one of the clinical trials including Remdesivir

investigation as a potential treatment for CoVid-19, we would like to make this information available to the IRB for further evaluation and consideration.

Respectfully,

Dr. Fleming

--

Richard M Fleming, PhD, MD, JD

(C) (b)(6)

(skype): fleming-reno

(email) (b)(6)

This electronic message is intended to be for the use of the named recipient, and may contain information that is confidential or privileged. This communication may contain protected health information (PHI) that is legally protected from inappropriate disclosure by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA) and relevant California Laws. You can direct questions concerning PHI or HIPAA to the Corporate Compliance and Privacy Officer at (818) 210-6930. If you are not the intended recipient, please note that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this message in error, you should notify the sender immediately by telephone or by return e-mail and delete and destroy all copies of this message.

From: (b)(6)
Sent: 5/16/2020 9:44:05 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Letter of request to receive remdesevir for my mother with severe case of Covid infection
Attachments: remdesevir EUA.pdf

May 16, 2020

Denise M. Hinton
Chief Scientist
Food and Drug Administration

Dear Ma'am:

This letter is in regards to your letter of authorization for emergency use of remdesevir for severe cases of hospitalized covid patients.

My name is (b)(6). I'm a Nurse Practitioner working in a primary care/urgent care office. I got infected of corona virus on (b)(6) which lasted two weeks then my husband got sick as well, we both stayed home and were able to manage. On (b)(6) my mother (b)(6) 69 years old got sick too and was tested positive for Covid on (b)(6). I thought we would be able to manage her symptoms at home but on (b)(6) (b)(6) she started to have respiratory distress and her oxygen level desaturated to 60s and 70s. I called 911 and she was brought to (b)(6). Right away was needed to have a high supply of oxygen, (non-rebreather and high flow oxygen). She was admitted that day and few days later she needed to be put on bipap. She was given Actemra twice and Plasma but no positive result. At this time, she is still at the hospital and has a really bad pneumonia. She requires a combination of non-rebreather and high flow oxygen at day time and bipap at night. On (b)(6) I saw your letter of authorization for emergency use of remdesevir for severe cases of hospitalized patients. In that letter, severe cases was defined as those with oxygen level of < 94 on room air, those who needs oxygen supplement and those who are intubated. Two days later after seeing this letter, I spoke to my mother's doctor, to the Infectious Disease Specialist who can prescribe this medication and requested that my mother be given remdesevir based on the criteria described. I was told that my mother doesn't fit the criteria because they are only giving it to intubated patients. But why would they have to wait for the patient to get intubated before giving the remdesevir? In some hospitals and trials they are giving this to severe cases with the goal of avoiding intubation and so far has positive outcome.

My mother has been at the hospital for over three weeks with no clinical improvement. I appreciate their effort of delaying intubation and all the care that my mother receives but I'm also requesting that she receives remdesevir treatment. In your letter, it was also mentioned that for non-intubated patient, they can get the 5 day dosing and if no improvement can extend up to 10 days.

Am I wrong to request remdesevir treatment for my mother? She is suffering and can barely eat because she can't breathe when she takes off the non-rebreather if she is only on high flow oxygen. I understand that there is no treatment for corona virus infection and all of the treatments are at clinical trial stage. The remdesevir so far based on the clinical trial sponsored by National Institute of Allergy and Infectious Disease (NIAID) has shown faster recovery of patient with advanced covid cases. I just hope that it's not late for my mother to receive remdesevir. She is on her 4th week since her symptoms started. At this point with no clinical improvement in her condition, why can we try all possible treatment to make her better?

I am writing this letter to advocate for my mother and possibly for all other covid patients with severe cases who have met the criteria to receive possible treatment but hospitals are not willing to provide it.

My mother, (b)(6) located at (b)(6) with telephone number (b)(6) I'm hopeful that she would be home by then.

I appreciate your prompt response to this letter. I'm not sure what else to do for my mother at this point, all I know is I would like her to survive and recover from this corona virus infection.

If you have any question or inquiry, I can be reach at my work number Monday to Friday from 9:00 am to 5:00 pm and out of office hours through my cellphone at (b)(6) You can also email me at (b)(6)

Please see attached copy of your letter of authorization for emergency use of remdesevir for patient with severe covid cases.

Thank you very much.

Sincerely,

(b)(6)

Sent: 5/20/2020 8:47:56 AM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
Subject: Question re: COVID-19- Famotidine Histamine Mast Cells and Mechanisms v3.4 19May.pdf
Attachments: COVID-19- Famotidine Histamine Mast Cells and Mechanisms v3.4 19May.pdf

Good morning Patrizia,

I received the following draft manuscript for review and am sending to you for awareness. Any concerns with this moving forward for publication?

From: Weichold, Frank <Frank.Weichold@fda.hhs.gov>
Sent: Tuesday, May 19, 2020 4:24 PM
To: Welch, Alice <Alice.Welch@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>; Warren, Matthew <Matthew.Warren@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Bouri, Khaled <Khaled.Bouri@fda.hhs.gov>
Subject: COVID-19- Famotidine Histamine Mast Cells and Mechanisms v3.4 19May.pdf

Dear Colleagues,

Please find attached draft manuscript FYI and review in context of the ongoing work and collaboration regarding famotidine for COVID19.

Please send me any comments and suggestions by May 22 (COB). Your kind review, timely feedback and help are very much appreciated.

Hoping you and yours are well!

Best wishes.

Frank

301-661-7890

Sent: 5/28/2020 12:55:11 PM
To: Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]
Subject: Question re: COVID mobile testing assets

Hi Jeff

Please see below.

Thanks,
Denise

From: Schmoyer, Michael W. EOP/OSTP (b)(6)
Sent: Thursday, May 28, 2020 12:52 PM
To: Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: COVID mobile testing assets

Good afternoon Admirals-

Thoughts on below? (b)(5)
(b)(5)

V/R,
CAPT Schmoyer

Michael W. Schmoyer, PhD
Assistant Director for Biotechnology & Biosurveillance
National Security & International Affairs Division

Office of Science and Technology Policy (OSTP)
Executive Office of the President
The White House

(O) (202) 456-2144 / (C) (b)(6)
(U) (b)(6) / (JWICS) (b)(6)
<https://www.whitehouse.gov/ostp/>



From: Rodgers, Loren E. EOP/WHO (b)(6)
Sent: Thursday, May 28, 2020 12:15 PM
To: Schmoyer, Michael W. EOP/OSTP (b)(6)
Cc: Ludwig, Michael E. COL USA WHMO/WHMU (b)(6); Hartung, Charles S. CAPT USN WHMO/WHMU (b)(6)
Subject: COVID mobile testing assets

CAPT Schmoyer,

I have a question about:

(b)(5)

(b)(5)

Do you have a moment available for a consultation?

V/r

Loren

Loren Rodgers, PhD

Commander, US Public Health Service

Epidemiologist; TDY to WHMU

WHMU Mobile Phone: (b)(6)

CDC Mobile phone: (b)(6)

WHMU Email: (b)(6)

CDC Email: lrodders@cdc.gov

In Officio Salutis

From: Morgan, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD7D5FD26BF04D5AA9F3393C8D419685-MICHAEL.MOR]
Sent: 6/5/2020 6:54:51 AM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: A mysterious company's coronavirus papers in top medical journals may be unraveling | Science | AAAS

RADM,

Just wanted to put this on your radar as it is Hydroxychloroquine related. This is big news in the scientific community right now.

<https://www.sciencemag.org/news/2020/06/mysterious-company-s-coronavirus-papers-top-medical-journals-may-be-unraveling>

Best,

Mike

From: Davit Mrelashvili, MD [RMT/C] [drmmrelashvili@soctelemed.com]
Sent: 6/6/2020 2:43:57 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Re: Hydroxychloroquine EUA

Dear Dr. Hinton,

Hope this message finds you well.

My name is Davit Mrelashvili, and I am a physician with active medical licenses in 26 states and telemedicine practice in over 150 hospitals across the country.

I am writing you on behalf of myself and many of my colleagues involved in treating COVID-19 patients, as well as creating treatment guidelines nationally, and internationally.

Our recent concern has been the growing evidence regarding Hydroxychloroquine safety and efficacy in Covid-19 patients.

As you are aware, the initial (limited) data at earlier stages of pandemic was promising, and suggested that Hydroxychloroquine could be safe and effective in COVID-19 patients, that resulted in its acceptance at an EUA level. However recently there has been an inflow of surmounting higher quality data, that not only Hydroxychloroquine had no significance difference than placebo in terms of efficiency (in randomized controlled trials), but in some cases was associated with higher mortality (yet a clear direct link not established, yet).

Most recently the national randomized study of COVID-19 patients with multiple treatment options RECOVERY, closed the recruitment for Hydroxychloroquine given that same concern.

While we completely understand that FDA provides a general guidance, rather than mandating or directing any particular patient treatment (that is left to the treating physician), we are getting a significant amount of distrust from the families and pushback from the local health care authorities, why we are not offering one of the few allowed treatment options to COVID-19 patients (despite us having an evidence based practice that it should not be offered), as Hydroxychloroquine remains to have an FDA EUA.

Our respectful question/request to you is given the above, whether or not FDA is considering removing the EUA from Hydroxychloroquine in the near future. If not – please let us know that as well, in which case we perhaps will need to seek out more local resources to protect ourselves from increased chances of an unjust litigation from the families of the patients with unfortunate outcomes, as not using the FDA authorized treatment certainly increases the chances of it in high mortality conditions.

I can only imagine the amount of workload and correspondence that you are getting these days, and any response regarding above matter will be much appreciated.

Respectfully,

Davit Mrelashvili, MD

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 6/6/2020 11:06:05 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Decontamination Letters for signature
Attachments: Battelle-Amendment3-LoA.pdf; STERRAD Letter of Auth FDA 6.5.20.pdf; Duke LoA 6.5.20.pdf; SSS VHP LoA 6.5.20.pdf; Sterilucent LoA 6.5.20.pdf; Steris LoA 6.5.20.pdf; Stryker TSO3 VHP4 LoA 6.5.20.pdf

Hi Liz,

All have been signed. Please let me know if I missed any.

Thanks,
Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Saturday, June 6, 2020 7:52 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Decontamination Letters for signature

As we discussed yesterday, I am sending the attached letters of authorization for the 7 decontamination systems EUAs being reissued. These are ready for signature. I will send back to CDRH as complete packages after you sign. The 2 FFR EUAs will be coming in a separate e-mail.
Thanks!

Sent: 6/14/2020 9:30:08 AM
To: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: CLOSE HOLD: for review by AM: HCQ EUA, (b)(4)

Good morning. I also agree with Keagan's suggestion of a

(b)(5)

(b)(5)

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Sunday, June 14, 2020 9:02 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: CLOSE HOLD: for review by AM: HCQ EUA, (b)(4)

Good morning - I concur with Keagan's suggestion.

Just spoke to Stephanie regarding the

(b)(5)

(b)(5)

Internal confidential pre decisional draft deliberative

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: June 14, 2020 at 8:05:37 AM EDT
To: Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: CLOSE HOLD: for review by AM: HCQ EUA, (b)(4)

(b)(5)

Sent from my iPhone

On Jun 13, 2020, at 11:25 PM, Pines, Wayne * <Wayne.Pines@fda.hhs.gov> wrote:

Stephanie:

Suggestions:

(b)(5)

Hope these suggestions help. Thanks.

Wayne

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Date: June 13, 2020 at 8:48:04 PM EDT

To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Pines, Wayne * <Wayne.Pines@fda.hhs.gov>

Subject: RE: CLOSE HOLD: for review by AM: HCQ EUA, (b)(4)

Updated version of HCQ EUA PR (b)(5)

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccorno@fda.hhs.gov

From: Caccorno, Stephanie

Sent: Saturday, June 13, 2020 6:43 PM

To: Hahn, Stephen; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>

Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi (Heidi.Rebello@fda.hhs.gov) <Heidi.Rebello@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>

Subject: CLOSE HOLD: for review by AM: HCQ EUA; (b)(4)

Hi—

Two press releases for your review. Remdesivir fact sheet update. Plus HCQ EUA revocation. I appreciate review by 9am tomorrow so we can get to HHS/WH.

Also want to urge us to consider a:

(b)(5)

(b)(5)

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.344.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 6/15/2020 8:10:39 AM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]
CC: Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: Flag on off-label
Attachments: HCQ EUA PR 6.15.20_7am press release.docx

INTERNAL/DELIBERATIVE

CDER is posting a QA about HCQ action. One of the QAs says below about not recommending using HCQ/CQ. CDER SMEs flagged for me this morning because they feel QA is inconsistent with what we are saying in the PR.

I am ok proceeding as is because I sort of feel like we are talking about what is ultimately up to a physician, flagging for awareness.

Q. What if I am in the middle of treatment with hydroxychloroquine sulfate (HCQ) or chloroquine phosphate (CQ) for COVID-19 under the EUA? Can my treatment continue to completion?

(b)(5)

Press release:

Of note, FDA approved products may be prescribed by physicians for off-label uses if they determine it is appropriate for treating their patients, including for COVID-19. (b)(5)

(b)(5)

Stephanie Caccomo

Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 6/15/2020 10:31:27 AM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Signed: HCQ/CQ revocation letter for signature
Attachments: Hydroxy revocation clean.doc; Hydroxy revocation clean.pdf

Thanks Liz!

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, June 15, 2020 10:22 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: HCQ/CQ revocation letter for signature

Attached is the final letter ready for your signature. Thanks!

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration

From: Davit Mrelashvili, MD [RMT/C] [drmmrelashvili@soctelemed.com]
Sent: 6/15/2020 2:49:32 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fec0be0694803be6030e97c7b4adb-HINTOND]
Subject: Re: Hydroxychloroquine EUA

Dear Dr. Hinton,

Thank you very much for your consideration and understanding.

Regards,
Davit

On Jun 6, 2020, at 2:43 PM, Davit Mrelashvili, MD [RMT/C] <drmmrelashvili@soctelemed.com> wrote:

Dear Dr. Hinton,

Hope this message finds you well.

My name is Davit Mrelashvili, and I am a physician with active medical licenses in 26 states and telemedicine practice in over 150 hospitals across the country.

I am writing you on behalf of myself and many of my colleagues involved in treating COVID-19 patients, as well as creating treatment guidelines nationally, and internationally.

Our recent concern has been the growing evidence regarding Hydroxychloroquine safety and efficacy in Covid-19 patients.

As you are aware, the initial (limited) data at earlier stages of pandemic was promising, and suggested that Hydroxychloroquine could be safe and effective in COVID-19 patients, that resulted in its acceptance at an EUA level. However recently there has been an inflow of surmounting higher quality data, that not only Hydroxychloroquine had no significance difference than placebo in terms of efficiency (in randomized controlled trials), but in some cases was associated with higher mortality (yet a clear direct link not established, yet). Most recently the national randomized study of COVID-19 patients with multiple treatment options RECOVERY, closed the recruitment for Hydroxychloroquine given that same concern.

While we completely understand that FDA provides a general guidance, rather than mandating or directing any particular patient treatment (that is left to the treating physician), we are getting a significant amount of distrust from the families and pushback from the local health care authorities, why we are not offering one of the few allowed treatment options to COVID-19 patients (despite us having an evidence based practice that it should not be offered), as Hydroxychloroquine remains to have an FDA EUA.

Our respectful question/request to you is given the above, whether or not FDA is considering removing the EUA from Hydroxychloroquine in the near future. If not – please let us know that as well, in which case we perhaps will need to seek out more local resources to protect ourselves from increased chances of an unjust litigation from the families of the patients with unfortunate outcomes, as not using the FDA authorized treatment certainly increases the chances of it in high mortality conditions.

I can only imagine the amount of workload and correspondence that you are getting these days, and any response regarding above matter will be much appreciated.

Respectfully,

Davit Mrelashvili, MD

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 7/11/2020 12:11:31 PM
To: CDRH-COVID19 Surgical Masks [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=62f1069d3ac0493ebb77ce2a943bb85b-CDRH-COVID1]
Subject: Response requested re: Protective Barrier Enclosures

Thank you.

From: Chan, Peter <Peter.Chan@easternhealth.org.au>
Sent: Saturday, July 11, 2020 1:33 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Protective Barrier Enclosures

RADM Hinton:

I am an ICU Specialist in Melbourne, Australia. We were recently gifted a number of protective barrier enclosures which we have gone on to evaluate for aerosol exposure. Our results were recently published in Anaesthesia. (<https://onlinelibrary.wiley.com/doi/full/10.1111/anae.15188>)

In short, even though our study was small, the results were highly significant pointing towards PBEs increasing, not decreasing your risk of aerosol exposure. Given the increasing evidence of aerosols causing potential COVID infection, I ask that you highly reconsider the EUA for this device until more tests can be done.

I note in your letter that these devices were tested using methods similar to ours – I would suggest you potentially repeat your experiment with a volunteer that coughs, to better simulate in vivo conditions. The results may indeed sway your opinion on these devices as they stand.

Kind Regards,

Dr. Peter Chan
ICU Specialist
Eastern Health
Melbourne, VIC
Australia 3128

Sent from Mail for Windows 10

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From: Ross, Jennifer [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44AE562EA1D840A3ACA172D0CC23F368-ROSSJ]
Sent: 7/13/2020 3:55:02 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4a7b-HINTOND]
Subject: FW: For OCS Signature today; (b)(4)

Attachments: (b)(4)

Friendly reminder on this one

From: Ross, Jennifer
Sent: Monday, July 13, 2020 2:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature today; (b)(4)

(b)(4)

RADM Hinton,

Please sign this letter; (b)(4)

(b)(4)

This was submitted by CDRH and incorporates edits from OCC (P.Taylor) below.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov



From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Monday, July 13, 2020 1:49 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee

<Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Many thanks, Paige and Jennifer. Please see attached for the final, clean documents. Jennifer, the letter should be ready for RADM Hinton's signature.

Thanks,
Brittany

Brittany Schuck, Ph.D.

COVID-19 Response Team
Personalized Medicine Policy

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Tel: 301-796-5199



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From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Sent: Monday, July 13, 2020 1:37 PM

To: Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothv.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Sounds good to me.

From: Taylor, Paige <Paige.Taylor@fda.hhs.gov>

Sent: Monday, July 13, 2020 1:29 PM

To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothv.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft
(b)(4)

(b)(4)

We do not have any further comments on the memo. On the letter,

(b)(5)

(b)(5) Otherwise, no changes. So these are ready to finalize and send.

Thanks much

Paige

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>

Sent: Monday, July 13, 2020 12:29 PM

To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Many thanks, Jaycie and Jennifer.

We agree with the edits on the letter and memo. Please see attached for revised documents where we have addressed the comments in the letter and memo.

Please let us know if these can be cleaned up and finalized.

Thanks,
Brittany

Brittany Schuck, Ph.D.

COVID-19 Response Team
Personalized Medicine Policy

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Tel: 301-796-5199



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From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Sent: Monday, July 13, 2020 11:17 AM

To: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

I had only very minor couple things on the letter. Thanks, Jennifer

From: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

Sent: Monday, July 13, 2020 10:26 AM

To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Hi all,

Sending OCC comments on the letter and a couple additional minor edit to the memo. Let us know if you have questions.

Thanks,
Jaycie

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>

Sent: Sunday, July 12, 2020 3:05 PM

To: Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Hi Paige and team,

Please see attached for revisions to the memo where we have responded to the comments and made corresponding edits, as needed. We have also attached the draft letter for your review.

Please let us know of any additional comments/questions/edits.

Many thanks,
Brittany

Brittany Schuck, Ph.D.

COVID-19 Response Team
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From: Taylor, Paige <Paige.Taylor@fda.hhs.gov>
Sent: Friday, July 10, 2020 2:03 PM
To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft (b)(4)

(b)(4)

Our comments on the (b)(4) memo are attached. Thanks

Paige

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Friday, July 10, 2020 9:58 AM
To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft (b)(4)

(b)(4)

Good Morning OCC and OCET colleagues,

For OCC/OCET review and concurrence, please see attached for the draft (b)(4) for (b)(4). Also, per your request, we have attached the emails exchanged with the sponsor during interactive review.

The information and clinical and analytical validation data submitted in the EUA request and through interactive review are not adequate to support issuance of the EUA. As briefly discussed during our call on Wednesday, this one is similar to the (b)(4) memo/letter since the basis of the denial is that the sponsor has not provided adequate information to demonstrate their device is adequately validated for its intended use.

Issuance of this denial in the interest of protecting public health is a priority for CDRH.

Please let us know if you have any questions or would like to further discuss.

Best,
Brittany

Brittany Schuck, Ph.D.

*COVID-19 Response Team
Personalized Medicine Policy*

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From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 7/13/2020 3:58:48 PM
To: Ross, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c62700d4f34b9db362ff2b6af4b-SADOVEE]
Subject: Signed (b)(4)
(b)(4)
Attachments: (b)(4) docx;
pdf

Thank you

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, July 13, 2020 2:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature today (b)(4)
(b)(4)

RADM Hinton,

Please sign this letter to (b)(4)
(b)(4)

This was submitted by CDRH and incorporates edits from OCC (P.Taylor) below.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov



From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Monday, July 13, 2020 1:49 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Many thanks, Paige and Jennifer. Please see attached for the final, clean documents. Jennifer, the letter should be ready for RADM Hinton's signature.

Thanks,
Brittany

Brittany Schuck, Ph.D.

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Sent: Monday, July 13, 2020 1:37 PM

To: Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Sounds good to me.

From: Taylor, Paige <Paige.Taylor@fda.hhs.gov>

Sent: Monday, July 13, 2020 1:29 PM

To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J.

<don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

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(b)(4)

We do not have any further comments on the memo. On the letter

(b)(5)

(b)(5)

Otherwise, no changes. So these are ready to finalize and send.

Thanks much

Paige

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>

Sent: Monday, July 13, 2020 12:29 PM

To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Many thanks, Jaycie and Jennifer.

We agree with the edits on the letter and memo. Please see attached for revised documents where we have addressed the comments in the letter and memo.

Please let us know if these can be cleaned up and finalized.

Thanks,
Brittany

Brittany Schuck, Ph.D.

COVID-19 Response Team

Personalized Medicine Policy

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CDRH | Food and Drug Administration
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Tel: 301-796-5199



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From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Sent: Monday, July 13, 2020 11:17 AM

To: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

I had only very minor couple things on the letter. Thanks, Jennifer

From: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

Sent: Monday, July 13, 2020 10:26 AM

To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Hi all,

Sending OCC comments on the letter and a couple additional minor edit to the memo. Let us know if you have questions.

Thanks,
Jaycie

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>

Sent: Sunday, July 12, 2020 3:05 PM

To: Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Hi Paige and team,

Please see attached for revisions to the memo where we have responded to the comments and made corresponding edits, as needed. We have also attached the draft letter for your review.

Please let us know of any additional comments/questions/edits.

Many thanks,
Brittany

Brittany Schuck, Ph.D.

COVID-19 Response Team
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Tel: 301-796-5199



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From: Taylor, Paige <Paige.Taylor@fda.hhs.gov>

Sent: Friday, July 10, 2020 2:03 PM

To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Our comments on the (b)(4) memo are attached. Thanks

Paige

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>

Sent: Friday, July 10, 2020 9:58 AM

To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>

Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>

Subject: RE: FOR REVIEW: draft

(b)(4)

(b)(4)

Good Morning OCC and OCET colleagues,

For OCC/OCET review and concurrence, please see attached for the draft (b)(4) for (b)(4). Also, per your request, we have attached the emails exchanged with the sponsor during interactive review.

The information and clinical and analytical validation data submitted in the EUA request and through interactive review are not adequate to support issuance of the EUA. As briefly discussed during our call on Wednesday, this one is similar to the (b)(4) memo/letter since the basis of the denial is that the sponsor has not provided adequate information to demonstrate their device is adequately validated for its intended use.

Issuance of this denial in the interest of protecting public health is a priority for CDRH.

Please let us know if you have any questions or would like to further discuss.

Best,
Brittany

Brittany Schuck, Ph.D.

*COVID-19 Response Team
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