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**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 4/20/2020 12:08:52 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: Blunt/Alexander Doc  
**Attachments:** AlexanderBlunt Doc 4.19 FINAL.docx

Do you know if this ever got to Dr. Birx? I'm happy to get it to TAM just to be sure but wasn't sure if you or SH had any edits before it goes to WH folks

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**From:** Rom, Colin  
**Sent:** Sunday, April 19, 2020 3:16 PM  
**To:** 'Hahn, Stephen' <sh1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Subject:** Blunt/Alexander Doc

Attached is doc requested by Sens. Alexander and Blunt providing an update on potential therapies, tech, monitoring practices, and devices. Let me know what you all think

Thanks!

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**Sent:** 4/23/2020 5:20:36 PM  
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Abernethy, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c84171967c724ee799bb2658197086bc-Amy.Abernet]  
**CC:** 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]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Subject:** RE: PLEASE SEE: Vanity Fair Media Inquiry

Can we make sure we are loop

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**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Thursday, April 23, 2020 5:16 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: PLEASE SEE: Vanity Fair Media Inquiry

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**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Thursday, April 23, 2020 5:03 PM  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: PLEASE SEE: Vanity Fair Media Inquiry

Thanks, yes, we have language to that effect. Let me add and recirculate. Stacy, maybe we can connect again after AEG to discuss what you would share with the reporter.

For awareness, whomever is sharing this info, shared similar with Politico:

### **Trump team wanted 'nationwide' access to malaria drugs, ousted vaccine chief claims**

By Dan Diamond

04/23/2020 04:55 PM EDT

The Trump administration pushed for nationwide access to a malaria drug touted by President Donald Trump as a Covid-19 treatment “with limited physician oversight,” according to a person familiar with the allegations of Dr. Rick Bright, the HHS vaccine chief who was ousted from his position earlier this week.



Bright felt such a move was dangerous and responded by pushing for more clinical trials, the person said, but, under pressure from his superiors in the health department, eventually agreed to sign off on an emergency use authorization that allowed the Trump administration to acquire tens of millions of doses of chloroquine and hydroxychloroquine and distribute the medicines to some patients hospitalized for Covid-19.

Bright, who was pushed out this week as head of the Biomedical Advanced Research and Development Authority, is now alleging that he was sidelined after pushing back against the administration's demands.

The Department of Health and Human Services did not immediately respond to request for comment. POLITICO reported last month that career health officials had concerns about how Trump's fixation on malaria drugs was undermining the nation's response to the Covid-19 outbreak and that the White House was pressuring career health officials to prioritize the drug despite scant evidence. The drug was also championed by Trump allies like Oracle founder Larry Ellison and an array of Fox News contributors.

Bright's lawyers on Thursday said that they would soon file a whistleblower complaint with the HHS inspector general and decried what they said were Trump administration efforts to undercut Bright's credibility.

"In our filing we will make clear that Dr. Bright was sidelined for one reason only — because he resisted efforts to provide unfettered access to potentially dangerous drugs, including chloroquine, a drug promoted by the Administration as a panacea, but which is untested and possibly deadly when used improperly," Debra S. Katz and Lisa J. Banks said in a statement. "The facts and concerns raised by Dr. Bright are compelling and well-documented and soon they will be public."

Administration officials had discussed removing Bright from his post last year amid management complaints, according to interviews that POLITICO conducted in January, prior to the Covid-19 outbreak.

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**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Thursday, April 23, 2020 4:58 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hahn, Stephen <(b)(6)@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>  
**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: PLEASE SEE: Vanity Fair Media Inquiry

Also looping Amy in on this.

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**From:** Amin, Stacy  
**Sent:** Thursday, April 23, 2020 4:56 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hahn, Stephen <(b)(6)@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguri, Laura <Laura.Caliguri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: PLEASE SEE: Vanity Fair Media Inquiry

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**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

**Sent:** Thursday, April 23, 2020 4:48 PM

**To:** Hahn, Stephen <SH1@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

**Subject:** PLEASE SEE: Vanity Fair Media Inquiry

Hi all,

A reporter with Vanity Fair has reached out with a 7 p.m. deadline for a story they are writing about a Trump administration plan that was being established over the last six weeks to disseminate chloroquine drugs widely through drugstores with the use of an app designed by Oracle. They are asking for FDA input/comment on a couple of points noted below. I've included proposed responses, but open to suggested revisions.

- **FEMA documentation from early April appears to suggest that FDA commissioner Stephen Hahn supported making chloroquine drugs from the Strategic National Stockpile available to COVID-19 patients more widely, outside of hospital settings. Can the FDA comment on whether Commissioner Hahn supported an administration plan to distribute chloroquine drugs for treatment of COVID-19 patients to drugstores as well as hospitals?**

**(b)(5)**

- **Vanity Fair will report that in mid-to-late March, the FDA's chief counsel Stacy Amin worked to execute a White House plan that would have BARDA sponsor a chloroquine IND, and then have President Trump announce the use of an Oracle app that would help patients access chloroquine drugs and collect data on their treatment. Can the FDA comment on the nature of this plan, and whether the FDA had to waive any regulations in order to work towards execution of it?**

**(b)(5)**

Please let me know as soon as possible.

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



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**From:** Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]  
**Sent:** 4/28/2020 7:17:14 PM  
**To:** Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; 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]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** RE: Proposed tweets for MN visit

I can send to SH to confirm this accurately captures what he did today. I extrapolated from VP's earlier tweets so not certain.

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**From:** Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 7:10 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** RE: Proposed tweets for MN visit

That's definitely okay re: @VP. I saw some PBS video earlier today. He definitely did the walk and talk tour.

**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



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**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 7:06 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>  
**Subject:** Re: Proposed tweets for MN visit

Can we tag @VP also in front of his other handle ?

On Apr 28, 2020, at 19:00, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

If that's what he did, looks good to me.

Sent from my iPhone

On Apr 28, 2020, at 6:44 PM, Rebello, Heidi <[Heidi.Rebello@fda.hhs.gov](mailto:Heidi.Rebello@fda.hhs.gov)> wrote:

How is this?

Joined @Mike\_Pence and others in Minnesota today @mayocliniclabs to see first-hand their ongoing investigative efforts on serology diagnostic testing for #COVID19 under the National Expanded Access Treatment Protocol.

. @US\_FDA is supporting a national Expanded Access Program to collect and provide convalescent plasma to patients in need across the country. Plasma from recovered COVID-19 patients contains antibodies that may help fight the disease.

**From:** Cohen, Kenneth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=44F565B739EA4879BDC516CAF2E136BC-KENNETH.COH]  
**Sent:** 5/5/2020 8:50:37 AM  
**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]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Agnew, Ann (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=daa06163025f427aa913c47cafaf6589-HHS-Ann.Agn]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facffe0846fc-HHS-Judy.St]; Mango, Paul (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2fe1932caf0249d2a0c6af5fb82c9ec5-HHS-Paul.Ma]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Malliou, Ekaterini (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c57996fad6db44ecba5ab5c1dacf7e0a-HHS-Ekateri]  
**CC:** Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Rooths, Tarita [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9ea3aa705bda4ff98b5043488cc9688f-TRooths]  
**Subject:** COVID-19 FDA Guidance Tracker - May 5, 2020

### Documents under HHS review

(1) CDRH, Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency

- Implements section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 351 et seq.), as added by section 3121 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), as it relates to device shortages and potential device shortages occurring during the COVID-19 pandemic, for the duration of the COVID-19 public health emergency

(2) CVM, Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency

- Provides recommendations on the information sponsors should submit to the Center for Veterinary Medicine to report and mitigate drug shortages for the duration of the public health emergency.

**(b)(5)**

### Documents Cleared Since Last Tracker

(No documents to report.)

## **Documents under Development in FDA**

### **On Previous Tracker**

(4) CDER, COVID-19: Developing Drugs and Biological Products for Treatment or Prevention

- Assists sponsors in the clinical development of drugs for the treatment or prevention of COVID-19.

(5) CDER, General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products

- Provides general considerations to assist sponsors in preparing pre-investigational new drug application (pre-IND) meeting requests for COVID-19 related drugs for the duration of the public health emergency.

(6) CDER, Responding to COVID-19 Infection in Employees in Pharmaceutical Manufacturing

- Provides recommendations to pharmaceutical manufacturers to help prevent or mitigate adverse impacts on the safety and quality of drugs manufactured by an employee(s) who is confirmed as having COVID-19 infection, or, was exposed within the 14-day incubation period but is asymptomatic and the employee was directly involved in manufacturing drugs while infected or potentially infected.

### **DELIBERATIVE, INTERNAL, PRE-DECISIONAL**

Kenneth R. Cohen, MHSA, MPP

Director, Regulations Policy and Management Staff

Office of Policy

301-796-7001

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**From:** Waters, Cicely (OS/ASPR/OEA) [Cicely.Waters@hhs.gov]  
**Sent:** 5/6/2020 1:00:51 AM  
**To:** Stecker, Judy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e205440400ab4f629be1facfce0846fc-HHS-Judy.St]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Michael, Gretchen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9124cfb0a9114613a44e2269824f94e6-HHS-Gretche]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pratt, Michael (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=facc5c0e27c74fd4964699547a71849d-HHS-Michael]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Beck, Gary (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9eaf3460f2f04ef9a80298a7acd61e64-HHS-Gary.Be]; Moughalian, Jen C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Mou]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; Pinson, Alexander (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ecb96fc7294239b8b3d077ed5d219c-HHS-Alexand]; Lenihan, Keagan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]  
**Subject:** Rollout Plan: Remdesivir Donation/Distro  
**Attachments:** Donation of Remdesivir - Rollout Plan\_v1.docx

Hello, Team:

Please find attached a proposed rollout plan for the remdesivir donation and distribution. Note that the distribution details are not finalized. Once they are, the rollout plan can be updated to reflect -- should the decision be made to utilize this content.

Regards,  
Cicely

202 (b)(5)

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**From:** Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov>

**Sent:** Tuesday, May 5, 2020 10:09 PM

**To:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely



(OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pratt, Michael (OS/ASPA) <Michael.Pratt@hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Beck, Gary (OS/IEA) <Gary.Beck@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand (FDA/OC) <Anand.Shah@fda.hhs.gov>

**Cc:** Harrison, Brian (HHS/IOS) <Brian.Harrison@hhs.gov>

**Subject:** Re: Rollout

I'm adding FDA as well for their awareness.

Please get your inputs to ASPR (Cicely and Gretchen) and the number of calls and who needs to be reached out to and the SMEs that need to be available.

ASPR please put the times as tbd am and pm. This issue may now likely be elevated so no rollout go without explicit okay from WH please continue to build the plan and to clear the release.

Rollout doc (which should have appropriate draft/pre decisional work product Language) and release need to be cleared by OVP and WH Comms. Additionally the FEMA JIC should be engaged and appropriate FEMA counterparts working this draft rollout as they and others developed the allocation and ASPR is distributor.

We will convene for another touch base on this likely in the AM.

Thanks all!

Sent from my iPhone

On May 5, 2020, at 9:12 PM, Stecker, Judy (OS/IOS) <Judy.Stecker@hhs.gov> wrote:

Hi All,

Here is everyone in one place so we can communicate/circulate the tick tock. Please send materials as you have them.

Thanks,  
Ashton

-----Original Appointment-----

**From:** Pollard, Ashton (OS/IOS) **On Behalf Of** Stecker, Judy (OS/IOS)

**Sent:** Tuesday, May 5, 2020 8:16 PM

**To:** Stecker, Judy (OS/IOS); Arbes, Sarah (HHS/ASL) (Sarah.Arbes@hhs.gov); Michael, Gretchen (OS/ASPR/OEA); Murphy, Ryan (OS/ASPA); Shuy, Bryan (OS/ASPR/IO); Waters, Cicely (OS/ASPR/OEA); Oakley, Caitlin B. (OS/ASPA); Caputo, Michael (HHS/ASPA); Morse, Sara (HHS/ASL); Pratt, Michael (OS/ASPA); Johnston, Darcie (HHS/IEA); Pollard, Ashton (OS/IOS); Laura Trueman (Laura.Trueman@hhs.gov); Gary Beck (Gary.Beck@hhs.gov); Brian Harrison (brian.harrison@hhs.gov); Moughalian, Jen (HHS/ASFR) (Jen.Moughalian@hhs.gov); Caitrin Shuy (HHS/ASFR) (Caitrin.Shuy@hhs.gov); Alexander Pinson (HHS/ASFR) (Alexander.Pinson@hhs.gov)

**Subject:** Call with Judy

**When:** Tuesday, May 5, 2020 8:30 PM-9:00 PM (UTC-05:00) Eastern Time (US & Canada).

**Where:** 8668799812; (b)(6)

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 5/6/2020 8:17:39 AM  
**To:** Sigg, Jim [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37695069dc214f5cb20e6056dd4d7cf7-sigg]; Hebert, Angelique A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]  
**Subject:** Fwd: HHS COVID-19 Update, 5-4-2020

FYI - Some good recommendations for reopening to discuss with the group.

Sent from my iPhone

Begin forwarded message:

---

**From:** Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>  
**Date:** May 4, 2020 at 5:54:23 PM EDT  
**To:** Trueman, Laura (OS) <Laura.Trueman@hhs.gov>  
**Subject:** HHS COVID-19 Update, 5-4-2020

Dear Colleague:

As governors move forward on decisions to reopen some or parts of their states, the Administration continues to support them in a variety of ways. One way is by issuing guidances for the wide range of situations that are part of reopening. We also continue to work closely with states as they solidify their testing and contact tracing capabilities, working individually with them to address their needs. Today's updates fall heavily into these areas.

### Testing Updates

**Improving Antibody Testing Quality:** FDA has revised its policy to improve antibody testing quality. FDA is issuing this guidance to provide a policy to help accelerate the availability of novel coronavirus (COVID-19) tests developed by laboratories and commercial manufacturers for the duration of the public health emergency. This guidance describes a policy for laboratories and commercial manufacturers to help accelerate the use of tests they develop in order to achieve more rapid and widespread testing capacity in the United States. Under the new policy, FDA expects commercial manufacturers to submit Emergency Use Authorization (EUA) requests, including their validation data, within 10 days of publication of the updated policy or the date they notify FDA of their test validation, whichever is later. Additional information can be found in a fact sheet on antibody testing oversight and use for COVID-19, as well as in a blog posting that notes the new emphasis on prioritizing access and accuracy.

**Contact Tracing Training Guidance:** CDC released a training module on contact tracing. This web page contains a sample training plan including training topics that may be helpful for state and local public health jurisdictions to consider when designing their own training plan for COVID-19 contact tracers. Each heading represents the learning objective for that section. Suggested training modalities/formats are provided, as well as information about sample existing trainings and resources. This document may be updated as new resources become available.

**Information on Evaluation and Testing Patients:** CDC updated their guidance on evaluating and testing persons for COVID-19. The changes include updated recommendations for testing, specimen collection, and reporting patients and reporting positive test results, and specification of testing priorities.

**CDC Resources for Testing:** CDC released a new fact sheet on federal resources for COVID-19 contact tracing staff. This fact sheet describes several ways health departments can access additional staffing for COVID-19 contact tracing, including through State Service Commissions and AmeriCorps Programs, CDC, and FEMA.

**Information for Laboratories:** CDC updated their FAQ document for testing and reporting by laboratories. The FAQs include information on accessing laboratory testing, data and reporting, test developers, serology, and ordering supplies.

## **Treatment Updates**

**Symptom Based Strategy for Discontinuing Isolation:** CDC released a decision memo that outlines the updated recommendations for discontinuing isolation. In the context of community transmission where continued testing is impractical, available evidence at this time indicates that an interim strategy based on time-since-illness-onset and time-since-recovery can be implemented to establish the end of isolation. Practical application of a symptom-based strategy cannot prevent all infections.

**Updated Information on Discontinuing Isolation:** CDC also updated their discontinuation of isolation for persons with COVID-19 not in healthcare settings. This guidance is for healthcare providers and public health officials managing persons with COVID-19 under isolation who are not in healthcare settings. This includes, but is not limited to, at home, in a hotel or dormitory room, or in a group isolation facility. Updates include extending the home isolation period based on evidence suggesting a longer duration of viral shedding and will be revised as additional evidence becomes available. The clinical care guidance for health professionals and information on what to do if you are sick was also updated to reflect this change.

**Updates on Convalescent Plasma:** The FDA updated its guidance on convalescent plasma and associated web page. The updated guidance provides clarification for investigators on how to submit investigational applications for COVID-19 convalescent plasma. In addition, the guidance includes updated information regarding potential donors. Previously, the FDA's guidance noted that to qualify, individuals should have complete resolution of symptoms for 28 days or resolution for 14 and a negative diagnostic test. The revised guidance recommends that individuals have complete resolution of symptoms for at least 14 days prior to donation. A negative lab test for COVID-19 disease is not necessary to qualify for donation. The revised guidance also clarifies that FDA does not recommend storing a retention sample from the convalescent plasma donation for single patient emergency INDs.

**Expanding Dialysis Therapy Options:** To help address shortages of continuous renal replacement therapy (CRRT) products during the COVID-19 public health emergency, today the FDA issued an EUA to Fresenius Medical Care for emergency use of the multiFiltrate PRO System and multiBic/multiPlus Solutions. CRRT is a type of dialysis therapy used to filter and clean the blood when the kidneys are damaged or are not functioning normally. The Fresenius multiFiltrate PRO System and multiBic/multiPlus Solutions have been authorized to provide CRRT to treat patients in an acute care environment during the COVID-19 public health emergency.

**Additional Information on Remdesivir:** FDA released Frequently Asked Questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients. The FAQs cover EUA for the drug, the side effects, additional information about the uses and the study on Remdesivir and how to obtain the drug.

**Convalescent Plasma Guidance and Recommendations:** FDA updated their general guidance and recommendations on convalescent plasma. The guidance includes recommendations on pathways for use of plasma, patient eligibility, collection of convalescent plasma, and recordkeeping. Because COVID-19 convalescent plasma has not yet been approved for use by FDA, it is regulated as an investigational product. A health care provider must participate in one of the pathways described below. FDA does not collect COVID-19 convalescent plasma or provide COVID-19 convalescent plasma. Health care providers or acute care facilities should instead obtain COVID-19 convalescent plasma from an FDA-registered blood establishment.

**New Study on Coronavirus and Children:** NIAID announced a new study to determine incidence of novel coronavirus infection in US children. The study, called Human Epidemiology and Response to SARS-CoV-2 (HEROS), also will help

determine what percentage of children infected with SARS-CoV-2, the virus that causes COVID-19, develop symptoms of the disease. In addition, the HEROS study will examine whether rates of SARS-CoV-2 infection differ between children who have asthma or other allergic conditions and children who do not.

## **PPE and Supplies**

**PPE Shipments to Nursing Homes:** FEMA has released additional details in a fact sheet on PPE shipments to nursing homes. Announced last week, FEMA will coordinate two shipments totaling a 14-day supply of personal protective equipment (PPE) to more than 15,000 nursing homes across the Nation. Shipments are expected to begin in the first week of May and a second shipment will occur in June. Each facility will receive an allotment of surgical masks, gloves, goggles, and gowns. Each facility will receive an allotment of all four items based on the staff size of the facility.

## **Funding and Resources**

**\$40 Million to Support Education to Racial and Ethnic Minority and Vulnerable Communities:** The Office of Minority Health announced a competitive funding opportunity to invest up to \$40 million for the development and coordination of a strategic network of national, state, territorial, tribal and local organizations to deliver important COVID-19-related information to racial and ethnic minority, rural and socially vulnerable communities hardest hit by the pandemic. The information network will strengthen efforts to link communities to COVID-19 testing, healthcare and social services and to best share and implement effective response, recovery and resilience strategies. Applications are due by 6:00 PM Eastern Time on Monday, May 11.

**30 States Receive Assistance for Crisis Counseling:** FEMA announced approval of 30 states and the District of Columbia for its Crisis Counseling Assistance and Training program. The program helps fund state-provided crisis counseling services to residents struggling with stress and anxiety as a result of the coronavirus (COVID-19) pandemic. FEMA's Crisis Counseling program helps people and communities to recover from the effects of natural or man-made disasters through short-term interventions that provide emotional support, crisis counseling, and connection to familial and community support systems.

**\$200 Million to Local Jurisdictions for Hungry and Homeless Populations:** FEMA announced \$200 million in supplemental funding allocations to local jurisdictions across the country to supplement local service organizations that provide critical resources to people with economic emergencies, which include our hungry and homeless populations.

## **Information for General Populations:**

**COVID-19 At a Glance:** The FDA has also posted an updated COVID-19 Response At-A-Glance Summary. It contains updates on major agency activities as well as some important facts and figures.

**Tips about Grocery Shopping:** Given the many questions people have about grocery shopping safety, the FDA has posted a video, 12 Tips for Grocery Shopping During the Pandemic, to advise consumers.

## **Information for Specific Populations:**

**Tips for Healthcare Systems to Operative Effectively:** CDC released a new document with 10 ways healthcare systems can operate effectively during the covid-19 pandemic. This document provides practical approaches that can be used to protect healthcare personnel (HCP), patients, and communities. The tips include information on work safety and support, patient service delivery, data streams for situational awareness, facility practices and communications.

**Information on Caring for Someone at Home:** CDC updated their information on Caring for Someone Sick at Home or other non-healthcare setting. The guidance includes information on how to protect yourself and others. Advice includes learning what to do when someone has symptoms of COVID-19 or when someone has been diagnosed with the virus. This information also should be followed when caring for people who have tested positive but are not showing symptoms.

**Information for Pediatric Healthcare Providers:** CDC updated their resources for Pediatric Healthcare Providers on what to do when managing pediatric patients with suspected or confirmed COVID-19. The webpage has information on maintaining childhood immunizations during the pandemic, the burden of COVID-19 among children, the clinical presentation of COVID-19 in children, treatment and prevention for children, and additional resources.

**Information for Businesses:** CDC updated their FAQ document for businesses. The FAQs cover topics including suspected or confirmed cases in the workplace, reducing the spread in workplaces, healthy business operations, cleaning and disinfecting, critical infrastructure and additional resources.

**Information for Dentists:** CDC updated their infection prevention and control guidance for dental settings during the COVID-19 response. The key information notes that dental settings have unique characteristics that warrant additional infection control considerations and advises dentists to postpone elective procedures, surgeries, and non-urgent dental visits, proactively communicate to both staff and patients the need for them to stay at home if sick, and know steps to take if a patient with COVID-19 symptoms enters your facility. CDC recommends dentists actively screen patients and colleagues before every shift.

**Information for Community and Faith-based Organizations:** CDC updated their information for community and faith-based organizations in preparations for re-opening. The resources include information on ongoing mitigation guidance, prevention and support, and a webinar.

**Information for Veterinarians regarding Companion Animals:** CDC updated their interim infection prevention and control guidance for veterinary clinics treating companion animals during the covid-19 response. Updates were made to clarify PPE recommendations based on situational risk factors and guidance for returning to normal clinic practices.

**Information for Environmental Health Practitioners:** CDC posted information for specific environmental health practitioners including congregate facilities and shelters such as general population disaster shelters, correctional and detention facilities, retirement communities, childcare centers that remain open, cooling centers and more. This webpage provides information for environmental health practitioners from CDC and other trusted sources.

If you have questions, email [Gary.Beck@hhs.gov](mailto:Gary.Beck@hhs.gov).

Laura

Laura C. Trueman  
Director, Office of Intergovernmental and External Affairs  
U.S. Department of Health and Human Services  
200 Independence Avenue SW  
Washington D.C. 20201  
[Laura.Trueman@hhs.gov](mailto:Laura.Trueman@hhs.gov)  
202-690-6060 (main office)

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 5/7/2020 10:31:58 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]  
**Subject:** CovidVitals\_07 MAY 2020.docx  
**Attachments:** CovidVitals\_07 MAY 2020.docx; ATT00001.txt

Vitals for today

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**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 5/8/2020 7:59:32 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Talking Points - Sheila Kaplan at 8:30 a.m.  
**Attachments:** 0830-TPs Sheila Kaplan\_5.7.20\_11am.docx

Background for 8:30 a.m. Interview with Sheila Kaplan -

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 5/11/2020 9:48:36 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** CovidVitals\_11 MAY 2020.docx  
**Attachments:** CovidVitals\_11 MAY 2020.docx; ATT00001.txt



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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 5/12/2020 8:56:22 AM  
**To:** Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** Re: Temple University Hospital, Phila PA: Remdesivir

Thanks.

Sent from my iPhone

On May 12, 2020, at 8:53 AM, Shah, Anand <Anand.Shah@fda.hhs.gov> wrote:

Yes I will get this routed to the right folks at ASPR

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, May 11, 2020 6:25 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** Fwd: Temple University Hospital, Phila PA: Remdesivir

Can you pls manage? Thanks.

Sent from my iPhone

Begin forwarded message:

**From:** "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>  
**Date:** May 11, 2020 at 6:19:42 PM EDT  
**To:** Kristin Dini <kdini@temple.edu>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Temple University Hospital, Phila PA: Remdesivir

Kristin

I am connecting you to Keagan Lenihan, our Chief of Staff. I am recused from this issue and she can help you directly.

Thank you!

Laura

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**From:** Kristin Dini <kdini@temple.edu>  
**Sent:** Monday, May 11, 2020 10:26 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** Temple University Hospital, Phila PA: Remdesivir

Good morning, Laura.

Sean Bonyun from OSTP indicated he reached out to a few days ago regarding Temple University Hospital (TUH). Thank you for paying attention to this for us.

Im attaching a letter from our chief medical officer sent to the FEMA Administrator, Region III, on May 6 regarding the distribution of Remdesivir. TUH has been at the epicenter of the pandemic in Philadelphia, treating the most COVID patients of any hospital in the city. Temple University Hospital is situated in North Philadelphia. The community is one of

the most vulnerable in the city, and now, this pandemic threatens to exacerbate poverty and health disparities already facing these families. Further, TUH is the safety net provider for the city. You'll see additional COVID-19 specific data in the attached letter.

Additionally, TUH is participating in a Remdesivir clinical trial under the leadership of Dr. Gerard Criner, director Temple's Lung Center and Chair of the Thoracic Medicine and Surgery for Temple's School of Medicine.

With distribution of Remdesivir underway, we would like to be considered for receipt of this treatment.

Please let me know what else would be helpful in engaging on this. Happy to discuss over the phone. My cell is below.

Kristin

Kristin Dini  
Assistant Vice President  
Federal Relations  
Temple University  
Government Affairs & Civic Engagement  
750 First Street, NE Suite 1110  
Washington, DC 20002  
Office: (202) 216-4367  
Cell: (b)(6)

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**From:** Helms Williams, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=873BE46F1B1A4D2B8DF3FE67137CBDC8-HELMSWILLIA]  
**Sent:** 5/14/2020 3:14:32 PM  
**To:** 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:** FW: ANDA 212902 Approval Notification

FYI, the hydroxychloroquine ANDA has been approved.

---

**From:** Hennessey, Lyndsay <Lyndsay.Hennessey@fda.hhs.gov>  
**Sent:** Thursday, May 14, 2020 2:47 PM  
**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** McLatchy, Johanna <Johanna.McLatchy@fda.hhs.gov>  
**Subject:** FW: ANDA 212902 Approval Notification

fyi

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**From:** Derosales, Dustin <Dustin.Derosales@fda.hhs.gov>  
**Sent:** Thursday, May 14, 2020 2:19 PM  
**To:** CDER-OGDAPPROVALS <OGDAPPROVALS@fda.hhs.gov>  
**Cc:** Shin, Joe <Joe.Shin@fda.hhs.gov>; Kim, Andrew (CDER) <Andrew.Kim@fda.hhs.gov>  
**Subject:** ANDA 212902 Approval Notification

Good Afternoon,

The following Abbreviated New Drug Application has been **Fully Approved**. This ANDA is a Drug Shortage as well as a COVID-19 priority.

|   |  |
|---|--|
| ANDA #  | 212902   |
| Drug Name/Dosage Form/Strength                                      | Hydroxychloroquine Sulfate Tablets USP, 200 mg   |
| Approved Date   | May 14, 2020   |
| Indication(s)   | For the treatment of uncomplicated malaria due to <i>P. falciparum</i> , <i>P. malariae</i> , <i>P. ovale</i> , and <i>P. vivax</i> as well as prophylaxis of malaria in geographic areas where chloroquine resistance is not reported. It is also used for the treatment of chronic discoid lupus erythematosus and systemic lupus erythematosus as well as for acute and chronic rheumatoid arthritis in adults. |
| Applicant   | Havix Group Inc.   |
| RLD # and Name  | 009768; Plaquenil Tablets, 200 mg  |
| Regulatory Classification (RX-OTC)                                  | RX   |
| Reason for Priority/Noteworthy (Labeling issues/Exclusivity issues) | Drug Shortage and COVID-19 Priority  |

Thank you,

*Dustin DeRosales, Pharm D*

Regulatory Project Manager

Division of Project Management/OGD/FDA

10903 New Hampshire Avenue

WO 75, Room 3608

Silver Spring, MD 20993

301-796-1950

Dustin.Derosales@fda.hhs.gov

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 5/15/2020 5:47:38 AM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** CovidVitals\_14 MAY 2020.docx  
**Attachments:** CovidVitals\_14 MAY 2020.docx; ATT00001.txt

Vitals from Yesterday.

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 5/16/2020 9:11:08 AM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]  
**Subject:** CovidVitals\_15 MAY 2020.docx  
**Attachments:** CovidVitals\_15 MAY 2020.docx; ATT00001.txt

Vitals from yesterday.

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**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
**Sent:** 5/16/2020 9:48:22 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** FW: n95 PR EUA PR  
**Attachments:** draft\_PR\_N95s\_3.2.20\_535\_for PRN.docx

Found this in Daily Roundup, for the non-NIOSH facemasks

In response to this evolving public health emergency and continued filtering facepiece respirator (FFR or respirator) shortages, FDA has concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized respirators listed in Exhibit 1 are authorized for use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

- Letter of Authorization
- [Non-NIOSH Approved Respirator EUA FAQ](#)

**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](mailto:stephanie.caccomo@fda.hhs.gov)

---

**From:** Caccomo, Stephanie  
**Sent:** Saturday, May 16, 2020 9:39 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** n95 PR EUA PR

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 5/16/2020 2:22:41 PM  
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Subject:** Re: Flag for Monday

What's the update here?

Sent from my iPhone

On May 16, 2020, at 1:54 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Thanks for chat. Look forward to connecting on this one.

**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

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**From:** Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>  
**Date:** May 16, 2020 at 1:36:10 PM EDT  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, Caputo, Michael R (OS) <Michael.Caputo@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>  
**Cc:** Caliguirri, Laura <Laura.Caliguirri@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: Flag for Monday

Hey Stephanie – please HOLD on this. Do not proceed with Monday's plan.

Please let me know you've received.

Thanks,  
Ryan

---

**From:** Murphy, Ryan (OS/ASPA)  
**Sent:** Saturday, May 16, 2020 12:26 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Michael Caputo (HHS/ASPA) (Michael.Caputo@hhs.gov) <Michael.Caputo@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>  
**Cc:** Caliguirri, Laura (FDA/OC) <Laura.Caliguirri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>  
**Subject:** RE: Flag for Monday



+ Caputo and Caitlin

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**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Sent:** Friday, May 15, 2020 3:58 PM  
**To:** Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>  
**Cc:** Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>  
**Subject:** Flag for Monday

Hi folks—

Sara Murray at CNN is planning a series of stories on FDA. We are moving forward with a background chat for Dr. Hahn and Sara Monday morning. All of her questions (at bottom of email) are ones that Dr. Hahn has addressed before. Sara agreed that we would do a background chat and she could pull comments on the record with our permission.

This interview will most likely be part of a series of FDA stories—wide range of topics, including relationship with leadership, task force, diagnostics, treatments, inspections.

I had previously pinged Caitlin on this one, but I know this week was ridiculously busy. We are planning to proceed with our chat. Happy to talk through any concerns. CNN deadline is Monday, so we need to make this happen.

Thanks!  
Stephanie

**From:** Murray, Sara <Sara.Murray@cnn.com>  
**Sent:** Wednesday, May 13, 2020 7:36 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** Following up - CNN questions

Hi Stephanie,

Just following up with a better idea of questions we'd love get answers on for our FDA story. I put a sense of what I'm interested in chatting with Dr. Hahn about at the top. I'm sure he could answer the full list, but if you're game for putting other officials on the phone, I'm sure some of them could address the second set of questions. My colleague, Marshall Cohen, may join us if we are able to set up some calls (as long as you are okay with that). Thanks, and I look forward to hearing from you!

**For Dr. Hahn:**

It would be good to get a bit more color on what it was like to come into this job and immediately face a pandemic, plus his reaction when he realized he needed to self-quarantine and any color on what that experience has been like.

Are there people he has turned to for guidance throughout this? (Former FDA officials, counterparts abroad, doctors from previous points in his career, etc.?)

What are his interactions with the President like? He has said before that he hasn't felt any political pressure, can he talk a bit more about that, particularly since the President has been very vocal on steps he believes the FDA should take, etc.

Dr. Hahn was not included in the original coronavirus task force, led by Secretary Azar. Was that concerning at the time? Did that made it more difficult to get widespread testing up and running?

The President was quite public in his support of hydroxychloroquine before it was clear it would work. How do you strike the right balance between the President's prerogatives and staying true to the science?

Details from Bright's whistleblower complaint suggest that Dr. Hahn appeared to be on board in early April with making hydroxychloroquine available in pharmacies as well as hospitals. But ultimately the FDA reiterated guidance later that month that the drug should only be used under medical supervision and can have serious side effects. How did the FDA wind up at that conclusion?

Can you describe a bit more about the role the FDA is playing in Operation Warp Speed?

**For Dr. Hahn or others:**

When it came to diagnostic tests, the FDA was criticized for not loosening regulations quick enough. On antibody tests, the FDA was criticized for being too lax. How do you try to strike the right balance? Any lessons learned from this that can be applied moving forward?

Now that the FDA is not doing overseas testing, how do you ensure the drugs the US is importing (ie. Hydroxychloroquine from India) are safe?

As more studies show hydroxychloroquine is not effective against Covid-19, some have said it's time for the FDA to pull the EUA for the drug. Is the FDA considering that?

Has there been any effort to increase production/stockpile for remdesivir? What are the challenges around increasing production of this drug?

The FDA has said it's looking ahead to supply chain issues around a potential vaccine. What does that mean practically?

Also, how do you assure the vaccine is safe and effective if things are moving on this expedited time frame?

What moments stick out to you from an agency perspective? Days that you thought were major breakthroughs (particularly if there are things you think have been overlooked in media coverage)? Days where the agency felt like a punching bag?

**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

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**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 5/18/2020 8:02:28 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background information for 8:15 a.m. (05/17) Telecon Commissioner Prep: Background Chat w/CNN  
**Attachments:** 0815-CNN\_profile of FDA\_5.14.20.docx

Background information for 8:15 a.m. (05/17) Telecon Commissioner Prep: Background Chat w/CNN

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**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 5/19/2020 8:07:30 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**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]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]  
**Subject:** Re: NYT Follow-up

Here's the story. Actually pretty balanced, all things considered:

<https://www.nytimes.com/2020/05/19/us/politics/hydroxychloroquine-trump-coronavirus.html>

## **Amid Hydroxychloroquine Uproar, Real Studies of Drug Are Suffering**

The political fights around a malaria drug that President Trump says he takes daily have impeded studies into whether it works to prevent coronavirus infection or treat Covid-19 early.

**By Sheryl Gay Stolberg**

May 18, 2020

WASHINGTON — President Trump's enthusiastic embrace of a malaria drug that he now says he takes daily without proof that it is effective against Covid-19 — and the resulting uproar in the news media — appears to be interfering with legitimate scientific research into whether the medicine might work to prevent coronavirus infection or treat the disease in its early stages.

The drug, hydroxychloroquine, which is also widely used to treat lupus and other autoimmune diseases, has shown no real benefit for hospitalized coronavirus patients, and may have contributed to some deaths, recent studies show. Some bioethicists are even calling for the Food and Drug Administration — which has warned that the drug can cause heart problems — to revoke an emergency waiver it granted in March to accept millions of doses of hydroxychloroquine into the national stockpile for use in hospitals.

But specialists — including Dr. Anthony S. Fauci, the government's top infectious disease expert — say the jury is still out on whether the drug might help prevent infection or help patients avoid hospitalization. Mr. Trump's frequent pronouncements and misstatements — he has praised the drug as a “game changer” and a “miracle” — are only complicating matters, politicizing the drug and creating a frenzy in the news media that is impeding research.

“The virus is not Democrat or Republican, and hydroxychloroquine is not Democrat or Republican, and I’m just hopeful that people would allow us to finish our scientific work,” said Dr. William O’Neill, an interventional cardiologist at Henry Ford Hospital in Detroit, who is studying hydroxychloroquine as a prophylactic in health care workers.

“The worst thing in the world that would happen,” he added, “is that at the end of his epidemic, in late September, we don’t have a cure or a preventive because we let politics interfere with the scientific process.”

On Tuesday, Mr. Trump added to the uproar. Addressing reporters on Capitol Hill, he called the research on hospitalized patients “a Trump enemy statement.” Later, at the White House, he said he decided to take hydroxychloroquine after his valet tested positive for Covid-19 — and intended to do so for “a little while longer” because he viewed it as a “worthwhile line of defense” and was “very curious” about it.

“It’s gotten a bad reputation only because I’m promoting it,” the president added. “If anybody else were promoting it, they would say it’s the best thing ever.”

Last week, the National Institute of Allergy and Infectious Diseases, which Dr. Fauci leads, announced a 2,000-patient study to determine whether hydroxychloroquine, when combined with the antibiotic azithromycin, “can prevent hospitalization and death from Covid-19,” joining more than 50 other clinical trials involving hydroxychloroquine that are continuing in the United States.

UnitedHealth Group is conducting a much smaller study of hydroxychloroquine alone, but Dr. Deneen Vojta, the insurance giant’s executive vice president for research and development, said the controversy was depressing enrollment in their clinical trials.

“People who had already enrolled would say, ‘Now I’m afraid, I want to disenroll,’” Dr. Vojta said.

In a draft letter to the Journal of the American Medical Association, obtained by The New York Times, members of a research consortium complained that “negative media coverage” of hydroxychloroquine — in particular the studies showing it might have harmed hospitalized patients — “directly correlated” with a drop in enrollment in trials run by institutions including the University of Minnesota, the University of Washington, Columbia University in New York and Henry Ford Hospital.

“Healthy fear stimulates scientific discoveries; uncontrolled fear inhibits scientific advancements,” the researchers wrote. “Politics and sensationalized journalism must not interfere with the integrity of much needed clinical trials.”

Inside the White House, the president’s trade adviser, Peter Navarro, who is an enthusiast for hydroxychloroquine and has worked with the Federal Emergency Management Agency to steer 19 million pills from the stockpile to 14 coronavirus hot zones around the country, said “hydroxy hysteria” in the news media — not Mr. Trump — was to blame.

“Has the media’s war of hysteria on hydroxychloroquine killed people?” Mr. Navarro asked in an interview. “If the scientific evidence does indeed prove that the medicine has both prophylactic and therapeutic value, the answer is yes.”

While Mr. Navarro complained that “fake news and bad reporting” had resulted in a “dramatic drop in demand for hydroxy at hospitals,” Dr. Mitchell Katz, the president and chief executive of NYC Health and Hospitals, the nation’s largest municipal health system, said hospitals and doctors

became less interested in hydroxychloroquine after the F.D.A. approved another medicine, remdesivir, for treatment of Covid-19.

But Mr. Trump continued to champion hydroxychloroquine, prompting criticism even from his favorite television network: Fox News Channel, whose senior managing editor for health news, Dr. Manny Alvarez, called the president “highly irresponsible” for taking the drug.

Scientists have worried about politics impeding their research since long before Mr. Trump took office. But perhaps no president in modern history has gone to the lengths that Mr. Trump has to promote a specific, unproven medicine — and then announce he is taking it himself. Many experts are aghast.

“What I am concerned about is that it may lead people to overestimate the potential that it would help them — which is entirely unproven — and to underestimate the risks, which are known,” said Jesse L. Goodman, a former chief scientist at the F.D.A. who is calling for the agency to revoke its waiver. “I think that right now this drug should be used really only in the context of clinical trials.”

But the president’s promotion of the drug is making even that difficult. Dr. Adrian Hernandez, who directs the Clinical Research Institute at Duke University School of Medicine and has enrolled 550 health care workers in a clinical trial to study whether hydroxychloroquine is effective as a prophylactic, said Mr. Trump’s promotion of hydroxychloroquine “may have hurt public health.”

When Mr. Trump first began talking up hydroxychloroquine, Dr. Hernandez said, he faced questions about whether his study should be weighted toward giving the drug to more people than were receiving placebo. But the pendulum swung the other way, he said, after two studies showed ill effects.

When he started, he said, two-thirds of more than 12,000 health care workers who have signed up for a coronavirus registry were willing to participate in his study. Now, only half are.

“When we have this playing out in the media instead of the scientific and clinical communities, people don’t know what the right answer is, and so they will use what they hear the most through the media,” Dr. Hernandez said. “So it’s a Ping-Pong match, in terms of, is it good one day? Is it bad one day?”

Dr. Hernandez and others, including Dr. O’Neill, say that no study — even those conducted in hospitalized patients — has produced definitive results about hydroxychloroquine for the coronavirus, though several have suggested it could be harmful especially to patients with underlying heart conditions.

An analysis of veterans treated with hydroxychloroquine found that 28 percent of them died, compared with 11 percent who had routine care. Mr. Trump denounced it on Tuesday as the work of his enemies. A small study in Brazil of patients taking a high dose of chloroquine — a predecessor to hydroxychloroquine that researchers consider less safe — was stopped for safety reasons.

Dr. Christine Johnston, an associate professor of medicine at the University of Washington who is hoping to enroll 630 people in a trial examining the effectiveness of hydroxychloroquine in those recently infected, said many of her patients conflated the Brazil study with her drug. She, too, has seen a dip in enrollment.

“People put these things together in their minds but they are actually very different,” she said.

On April 24, the F.D.A. issued a warning about hydroxychloroquine and chloroquine, cautioning against their use “outside of the hospital setting or a clinical trial due to risk of heart rhythm problems.” An F.D.A. spokesman, Michael Felberbaum, said in a statement that the agency was continuing to evaluate its emergency use authorizations, or E.U.A.s, issued because of “the current public health emergency, including the E.U.A. regarding chloroquine and hydroxychloroquine, to determine whether they continue to meet the statutory criteria for issuance.”

More recently, a large observational study of 1,446 patients at New York-Presbyterian-Columbia University Hospital in New York City, published this month in the New England Journal of Medicine, found no clear benefit or risk to hydroxychloroquine.

The authors concluded that randomized controlled clinical trials — studies in which half the patients are given placebo, half are given the drug and neither the patients nor doctors know who is getting what — are needed.

“Studying it is exactly the right thing to do,” said Aaron S. Kesselheim, a professor of medicine at Harvard Medical School who is among those calling for the F.D.A. to revoke the waiver. “I don’t mind doing a well organized, definitive clinical trial. I think that would be very helpful. And heck if it turns out there is some activity then great. Then in that case we should figure out how to get to the people who need it as quickly as possible.”

**Michael Felberbaum**

*Senior Advisor*

**Office of Media Affairs**

**Office of External Affairs**

**U.S. Food and Drug Administration**

Tel: 240-402-9548 / Cell: 202-906-0229

michael.felberbaum@fda.hhs.gov

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**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

**Date:** May 19, 2020 at 7:40:43 PM EDT

**To:** Lenihan, Keagan <Keagan.Lenihan@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>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>

**Subject:** NYT Follow-up

Hi Keagan,

Just wanted to follow up on the NYT story that we’ve been working with Caputo and others at HHS on over the past two days. Stacy spoke with the reporter this AM and we’ve provided all of our previously cleared content on HCQ and the EUA. The reporter has decided to potentially pursue a story about the issue the Bright complaint/emails at a later date - I’ve explained that everything on this narrative has already been written about and that could impact whether she ultimately does a story on that.

Instead, today she is writing a similar story as all of the outlets have about POTUS’ use and politicization of the drug. I expect she’s going to mention the studies so far that have lacked clear efficacy and our safety concerns,

as well as calls from some to revoke the EUA (same narrative as WaPo from last week). Will flag when I see the story, but wanted to update you.

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



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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 5/20/2020 10:06:45 AM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Daniel VADM Abel [Daniel.B.Abel@uscg.mil]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** CovidVitals\_19 MAY 2020.docx  
**Attachments:** CovidVitals\_19 MAY 2020.docx; ATT00001.htm

Vitals for Yesterday

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 5/20/2020 11:28:35 AM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**CC:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

Thx

Sent from my iPhone

On May 20, 2020, at 11:21 AM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Yes.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:08 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

(b)(5)

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**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:03 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Attached and below are your REVISED TPs for today's call and reupping agenda for reading. Hat tip to Molly for stepping in. Note no Q&A. You can drop after your remarks.

## THE WHITE HOUSE

### COVID-19 IGA State-Local Stakeholder Call

**WHEN:** Wednesday, May 20, 2020  
2:00 p.m. – 3:00 p.m.

**DIAL-IN:** *Speakers-Only*  
Dial-In: 877-369-5243  
Code: (b)(6)

**PURPOSE:** To continue coordination with State and local officials regarding the Administration's response to COVID-19, the implementation of the CARES Act and to provide pertinent Task Force and Agency updates.

**AUDIENCE:** Approximately ~3,000 State and local elected officials, including Governors/Governor staff, Attorneys General, Secretaries of State, mayors and city councilmembers, county commissioners, law enforcement, and local public health officials.

**BACKGROUND:** Federal officials have been working diligently to communicate with State, local, and tribal officials on the Federal government's efforts to prepare and respond to COVID-19 and underscore the importance of the partnership at every level of government. Outreach has included national briefing calls with stakeholders, coordination with relevant associations, and significant direct coordination with the most-impacted states and communities. Participants have included the President, Vice President, White House Coronavirus Task Force members, and other Senior Administration Officials.

**AGENDA:** *Remarks should be kept to approximately 5-10 minutes. There is no Q/A.*

**I. Welcome and Introduction**

- i. Doug Hoelscher, *Deputy Assistant to the President & Director, White House Office of Intergovernmental Affairs (IGA)*
- ii. First Lady Melania Trump, *The White House*

**II. Testing Update**

- i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*
- ii. Stephen Hahn, *Commissioner, U.S. Food & Drug Administration*

**III. Economic and Social Services Support Update**

- i. Brooke Rollins, *Office of American Innovation*
- ii. *TBD, Office of Economic Initiatives and Entrepreneurship*

**IV. Closing Remarks**

**May 19, 2020, Talking Points on Serology Testing**

**(b)(5)**

**(b)(5)**

**(b)(5)**

**(b)(5)**

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**From:** Caliguiri, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=AA086F2D6C0346C49E996932D86AC62E-LAURA.CALIG]  
**Sent:** 5/20/2020 12:01:18 PM  
**To:** Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; 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]  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

We will send to him as well.

---

**From:** Block, Molly <Molly.Block@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:47 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Updated. It's just under 1000 words, which should clock in between 6-7 minutes.

---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:33 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Just made edits sending next. 2 pm

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:30 AM  
**To:** Block, Molly <Molly.Block@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

Yield to you all, just want to make sure he doesn't have too much. Pls get it back to him when you all are comfortable. When is this call?

Sent from my iPhone

On May 20, 2020, at 11:28 AM, Block, Molly <Molly.Block@fda.hhs.gov> wrote:

With deletion suggestions. Attached would cut down approx. words. Let me know if more should be cut.

---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:22 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Yes.

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:08 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

(b)(5)

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**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:03 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

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Code: (b)(6)

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- i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*
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**III. Economic and Social Services Support Update**

- i. Brooke Rollins, *Office of American Innovation*
- ii. TBD, *Office of Economic Initiatives and Entrepreneurship*

**IV. Closing Remarks**

**May 19, 2020, Talking Points on Serology Testing**

**(b)(5)**

**(b)(5)**

**(b)(5)**

<5.20.20 IGA Call Talkers deletion suggestions.docx>

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 5/20/2020 12:13:00 PM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

Yes. No idea. Think detail.

Sent from my iPhone

On May 20, 2020, at 11:35 AM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Dropping the others, we have an ongoing disconnect on things with IGA and White House. Next round, would you  
[redacted] (b)(5) [redacted] Is Nick's job permanent or  
detail?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:30 AM  
**To:** Block, Molly <Molly.Block@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

Yield to you all, just want to make sure he doesn't have too much. Pls get it back to him when you all are comfortable. When is this call?

Sent from my iPhone

On May 20, 2020, at 11:28 AM, Block, Molly <Molly.Block@fda.hhs.gov> wrote:

With deletion suggestions. Attached would cut down approx. words. Let me know if more should be cut.

---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:22 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Yes.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:08 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

(b)(5)

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:03 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Attached and below are your REVISED TPs for today's call and reupping agenda for reading. Hat tip to Molly for stepping in. Note no Q&A. You can drop after your remarks.

## THE WHITE HOUSE

### COVID-19 IGA State-Local Stakeholder Call

**WHEN:** Wednesday, May 20, 2020  
2:00 p.m. – 3:00 p.m.

**DIAL-IN:** *Speakers-Only*  
Dial-In: 877-369-5243  
Code: (b)(6)

**PURPOSE:** To continue coordination with State and local officials regarding the Administration's response to COVID-19, the implementation of the CARES Act and to provide pertinent Task Force and Agency updates.

**AUDIENCE:** Approximately ~3,000 State and local elected officials, including Governors/Governor staff, Attorneys General, Secretaries of State, mayors and city councilmembers, county commissioners, law enforcement, and local public health officials.

**BACKGROUND:** Federal officials have been working diligently to communicate with State, local, and tribal officials on the Federal government's efforts to prepare and respond to COVID-19 and underscore the importance of the partnership at every level of government. Outreach has included national briefing calls with stakeholders, coordination with relevant associations, and significant direct coordination with the most-impacted states and communities. Participants have included the President, Vice President, White House Coronavirus Task Force members, and other Senior Administration Officials.

**AGENDA:** *Remarks should be kept to approximately 5-10 minutes. There is no Q/A.*

- I. **Welcome and Introduction**
  - i. Doug Hoelscher, *Deputy Assistant to the President & Director, White House Office of Intergovernmental Affairs (IGA)*
  - ii. First Lady Melania Trump, *The White House*
- II. **Testing Update**
  - i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*
  - ii. Stephen Hahn, *Commissioner, U.S. Food & Drug Administration*
- III. **Economic and Social Services Support Update**
  - i. Brooke Rollins, *Office of American Innovation*
  - ii. TBD, *Office of Economic Initiatives and Entrepreneurship*
- IV. **Closing Remarks**

**(b)(5)**

**(b)(5)**

**(b)(5)**

<5.20.20 IGA Call Talkers deletion suggestions.docx>



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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 5/20/2020 12:26:15 PM  
**To:** Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**CC:** Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

Thanks Molly!

Sent from my iPhone

On May 20, 2020, at 12:23 PM, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov> wrote:

Done plus heads up text from Molly

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 12:13 PM  
**To:** Block, Molly <Molly.Block@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

Thanks. Pls resend to him.

Sent from my iPhone

On May 20, 2020, at 11:47 AM, Block, Molly <Molly.Block@fda.hhs.gov> wrote:

Updated. It's just under 1000 words, which should clock in between 6-7 minutes.

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**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:33 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Just made edits sending next. 2 pm

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:30 AM  
**To:** Block, Molly <Molly.Block@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: WH Call TPs for today's state/local call (REVISED)

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---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:22 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

Yes.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:08 AM  
**To:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

(b)(5)

---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 11:03 AM  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>  
**Subject:** RE: WH Call TPs for today's state/local call (REVISED)

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### COVID-19 IGA State-Local Stakeholder Call

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- ii. First Lady Melania Trump, *The White House*

**II. Testing Update**

- i. Alex Azar, *Secretary, U.S. Department of Health and Human Services (HHS)*
- ii. Stephen Hahn, *Commissioner, U.S. Food & Drug Administration*

**III. Economic and Social Services Support Update**

- i. Brooke Rollins, *Office of American Innovation*
- ii. *TBD, Office of Economic Initiatives and Entrepreneurship*

**IV. Closing Remarks**

**May 19, 2020, Talking Points on Serology Testing**

**(b)(5)**

**(b)(5)**

**(b)(5)**

**(b)(5)**

<5.20.20 IGA Call Talkers deletion suggestions.docx>

<5.20.20 IGA Call Talkers 1145 am.docx>

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**Sent:** 5/27/2020 3:48:03 PM  
**To:** 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]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; 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]  
**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]; 'Wayne Pines (wpines@apcoworldwide.com)' [wpines@apcoworldwide.com]  
**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

Giid with me.

---

**From:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Sent:** Wednesday, May 27, 2020 3:23 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@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>; 'Wayne Pines (wpines@apcoworldwide.com)' <wpines@apcoworldwide.com>  
**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

Hi all—

I had a chance to talk to Dr. Hahn about the inquiries we've received and his thoughts on approach. I think Patrizia addition best captures what he recommends, I added a little bit below. Ok to proceed with this?

*"FDA has been closely monitoring new information from studies of hydroxychloroquine sulfate or chloroquine phosphate and COVID-19 as it emerges, to determine whether it warrants a revision of the benefit-risk assessment as described in the EUA. As it is our established practice, further action, if warranted, will be data driven and informed by scientific data from robust clinical trial results, such as randomized clinical trials."*

Possible to let us know in next hour so we can move this?

**Stephanie Caccomo**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.348.1256  
Cell: (b)(6)  
stephanie.caccomo@fda.hhs.gov

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Wednesday, May 27, 2020 1:10 PM  
**To:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@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>; Caccomo, Stephanie

<Stephanie.Caccomo@fda.hhs.gov>; 'Wayne Pines (wpines@apcoworldwide.com)' <wpines@apcoworldwide.com>  
**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

Those edits work for me – OK with others before I run by OCC? Thanks!

---

**From:** Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Sent:** Wednesday, May 27, 2020 12:59 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@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>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; 'Wayne Pines (wpines@apcoworldwide.com)' <wpines@apcoworldwide.com>  
**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

See suggested edits

Patrizia

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**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Wednesday, May 27, 2020 12:20 PM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; 'Wayne Pines (wpines@apcoworldwide.com)' <wpines@apcoworldwide.com>  
**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

Re-upping as we have several inquiries related to this. Thanks!

---

**From:** Felberbaum, Michael  
**Sent:** Wednesday, May 27, 2020 10:52 AM  
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; 'Wayne Pines (wpines@apcoworldwide.com)' <wpines@apcoworldwide.com>  
**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

+ Wayne

(b)(5)



(b)(5)

**From:** Rom, Colin <Colin.Rom@fda.hhs.gov>

**Sent:** Wednesday, May 27, 2020 10:23 AM

**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

(b)(5)

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>

**Sent:** Wednesday, May 27, 2020 10:20 AM

**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

**Subject:** RE: FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

+Colin

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

**Sent:** Wednesday, May 27, 2020 10:16 AM

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>

**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

**Subject:** FYI from Politico -- Fauci: Hydroxychloroquine not effective against coronavirus

Hi all,

Sharing the below from Politico, and flagging that others have reached out to asking regarding the EUA in relation to these comments and recent developments from WHO and Lancet study. We have the following cleared response, but wanted to confirm this response with this group.

(b)(5)

(b)(5)

Please let me know ASAP as we have several inquiries.

Thanks,

Michael

**Fauci: Hydroxychloroquine not effective against coronavirus**

By Zachary Brennan

05/27/2020 10:03 AM EDT

National Institute of Allergy and Infectious Diseases Director Tony Fauci on Wednesday became the first Trump administration official to say definitively that hydroxychloroquine is not an effective treatment for the coronavirus, based on the available data.

"The scientific data is really quite evident now about the lack of efficacy," Fauci — the U.S. government's top infectious disease expert — said on CNN.

But he stopped short of calling for an outright ban of the drug, which President Trump said he was taking last week as a preventative measure after a top White House aide was diagnosed with the coronavirus.

Fauci's comments come days after the Lancet published a 96,000-patient observational study that concluded that hydroxychloroquine had no effect on Covid-19 and may have even caused some harm.

France decided this week to ban the use of hydroxychloroquine, even in clinical trials, and the WHO has paused its clinical trials of the drug.

There is no data yet from randomized, controlled clinical trials of hydroxychloroquine — the gold standard for evaluating potential treatments. But Fauci was unequivocal on Wednesday, saying that "the data are clear right now."

**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:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 5/28/2020 8:23:56 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 95\_CovidVitals\_28 MAY 2020.docx  
**Attachments:** 95\_CovidVitals\_28 MAY 2020.docx; ATT00001.txt

FDA Vitals for today.

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**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 5/28/2020 8:51:56 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**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]; Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Pines, Wayne \* [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]  
**Subject:** CDER paper in Frontiers in Immunology on COVID therapies being evaluated  
**Attachments:** Press Release draft\_puig\_reviewed-5-25-20\_edited.docx; Author's Proof.pdf; Cardone et al.\_Supplementary Table\_Reviewed with Ref\_05152020.pdf

Hi both –

Flagging for awareness the attached scientific paper authored by researchers in CDER – which reviews key immunological factors underlying COVID-19 disease progression and outlines a range of existing drugs that are being studied to treat the disease. The paper was accepted by Frontiers in Immunology on April 29, so it is a bit dated given the pace that these studies are progressing (which is noted in the paper). The journal is issuing a press release as well, which quotes the main author. CDER did not make us aware of this paper, the press release or timing for publication. We'll work with CDER if we get any incoming Qs.

Thanks,

Michael

**Michael Felberbaum**

*Senior Advisor*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration

Tel: 240-402-5448 / Cell: (b)(6)  
michael.felberbaum@fda.hhs.gov



---

**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 5/29/2020 7:46:57 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background information for 8:00 a.m. Telecon Media Interview: Chris Stigall (Philadelphia's Morning Answer with Chris Stigall)  
**Attachments:** 0800+0830-Friday May 29 Radio Interview TPs.docx

Background information for 8:00 a.m. Telecon Media Interview: Chris Stigall (Philadelphia's Morning Answer with Chris Stigall)

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**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 5/29/2020 7:52:08 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background information for 8:30 a.m. Telecon Media Interview: Sam Malone, The Sam Malone Show (Houston, TX)  
**Attachments:** 0800+0830-Friday May 29 Radio Interview TPs.docx

Background information for 8:30 a.m. Telecon Media Interview: Sam Malone, The Sam Malone Show (Houston, TX)

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**From:** Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]  
**Sent:** 6/2/2020 4:54:24 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: FYI -- Lancet editors published an Expression of Concern re: CQ/HCQ outcomes registry analysis

They didn't specify, but yes, it's likely that there is something flawed in the data or the analysis that may change the conclusions of the paper.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Tuesday, June 02, 2020 4:52 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Subject:** Re: FYI -- Lancet editors published an Expression of Concern re: CQ/HCQ outcomes registry analysis

Does that mean study is no good?

Sent from my iPhone

On Jun 2, 2020, at 4:50 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

## **Expression of concern: Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis**

Important scientific questions have been raised about data reported in the paper by Mandeep Mehra et al— Hydroxychloroquine or chloroquine with or without a macrolide for treatment of COVID-19: a multinational registry analysis<sup>1</sup>—published in *The Lancet* on May 22, 2020. Although an independent audit of the provenance and validity of the data has been commissioned by the authors not affiliated with Surgisphere and is ongoing, with results expected very shortly, we are issuing an Expression of Concern to alert readers to the fact that serious scientific questions have been brought to our attention. We will update this notice as soon as we have further information.

*The Lancet Editors*

**Michael Felberbaum**  
*Senior Advisor*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-9548 / Cell: 202-906-0229  
michael.felberbaum@fda.hhs.gov

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/2/2020 9:44:23 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 98\_CovidVitals\_02 JUNE 2020.docx  
**Attachments:** 98\_CovidVitals\_02 JUNE 2020.docx; ATT00001.txt

Vitals for today.



---

**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 6/3/2020 10:37:26 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background material for 11:00 a.m. Weekly CBER Meeting with the Commissioner  
**Attachments:** 1100-CBER Weekly Meeting Agenda\_20200603.docx

Background material for 11:00 a.m. Weekly CBER Meeting with the Commissioner

---

**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 6/5/2020 7:38:53 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background for Radio Interview: Tony Katz show, Indianapolis, WIBC (On Air 7:42 AM)  
**Attachments:** 0740-0805-Friday June 4\_TPs.docx

Background material for Radio Interview: Tony Katz show, Indianapolis, WIBC (On Air 7:42 AM)

Tony Katz show, Indianapolis, WIBC

Call in by 7:40am

On air 7:42am for 10 minutes.

Call in [redacted] (b)(6) [redacted]

---

**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 6/5/2020 7:53:44 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background information for 8:05 a.m. Radio Interview: WSAU, Stevens Point, Wisconsin (Central/North Wisconsin), WSAU Wisconsin Morning News (Segment starts 8:10-8:20 AM)  
**Attachments:** 0740-0805-Friday June 4\_TPs.docx

Background information for 8:05 a.m. Radio Interview: WSAU, Stevens Point, Wisconsin (Central/North Wisconsin), WSAU Wisconsin Morning News (Segment starts 8:10-8:20 AM)

WSAU, Stevens Point, Wisconsin (Central/North Wisconsin)

Show: WSAU Wisconsin Morning News

Dr. Hahn should call (b)(6)

Call between 8:05 and 8:10 am

Segment starts at 8:10am—lasts approx. 10 min

Main host: Ben; other hosts: Chris and Tom

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/5/2020 9:34:25 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 101\_CovidVitals\_05 JUNE 2020.docx  
**Attachments:** 101\_CovidVitals\_05 JUNE 2020.docx; ATT00001.txt

Vitals for today.

---

**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** FW: CDC Guidance  
**Attachments:** NH Doc\_OMB and HHS Comments 6.6.20\_track.docx

See CDRH response below. I have added Anand and OCC to this chain and asked him to work with CMS to see if the suggested language would cover CMS's needs

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

From: Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>  
Sent: Tuesday, June 9, 2020 9:16 AM  
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
Subject: RE: CDC Guidance

Hello Keagan,

OCC changed the language in the CDC document about testing in nursing homes yesterday.

(b)(5)

Please let me know if you have any questions or if I need to provide additional comments to the JIC.

Thanks,  
Ellen

Ellen J. Flannery, J.D.  
Deputy Center Director for Policy  
Director, Office of Policy  
Center for Devices and Radiological Health Office of Policy U.S. Food and Drug Administration  
Tel: 301-796-5900  
Ellen.Flannery@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>

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

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
Sent: Tuesday, June 9, 2020 8:44 AM  
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>  
Subject: RE: CDC Guidance

Adding Ellen

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
Sent: Tuesday, June 9, 2020 8:29 AM  
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
Subject: CDC Guidance

Good Morning,

HHS is pinging us about a CDC guidance that is going through clearance on diagnostic testing. I believe it's for clarification for payment, but apologies I have limited info. Apparently, (b)(5)

(b)(5)

Do you all know about this? Can we leave it as can someone explain to me why it does?

(b)(5)

Thanks,  
Keagan

Sent from my iPhone

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/9/2020 10:08:48 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniel]  
**Subject:** 103\_CovidVitals\_09 JUNE 2020.docx  
**Attachments:** 103\_CovidVitals\_09 JUNE 2020.docx; ATT00001.txt

Vitals for today.

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/11/2020 5:56:47 PM  
**To:** Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** FW: convalescent plasma donations talkers...

Go to JW and PM for help, pls.

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Thursday, June 11, 2020 5: 52PM  
**To:** Troye, Olivia EOP/ NSC (b)(6)  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: convalescent plasma donations talkers...

Olivia,  
Very happy to help. Great to hear from you.  
Colin,  
Can you run the traps on this?  
Thanks  
Steve

---

**From:** Troye, Olivia EOP/ NSC (b)(6)  
**Date:** June 11, 2020 at 5:36:41 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Cc:** Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** convalescent plasma donations talkers...  
**Importance:** High

Dr. Hahn,

During the task force meeting, we discussed the (b)(5)

(b)(5)

Thank you in advance for your help!!

1. If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma.
2. Because you fought the infection, your plasma now contains COVID-19 antibodies. These antibodies provided one way for your immune system to fight the virus when you were sick, so your plasma may be able to be used to help others fight off the disease.
3. We encourage Americans who have been fully recovered for at least two weeks, to consider donating plasma.

Olivia Troye  
Special Advisor for Homeland Security, Counterterrorism & North America  
Office of the Vice President  
White House Coronavirus Task Force  
Office: (202) 456-2641  
Mobile: (b)(6) (Does not receive texts)



---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/11/2020 8:51:20 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 105\_CovidVitals\_11 JUNE 2020.docx  
**Attachments:** 105\_CovidVitals\_11 JUNE 2020.docx; ATT00001.txt

Vitals for today.

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 6/15/2020 11:24:28 AM  
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**CC:** Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

Pls!

Sent from my iPhone

On Jun 15, 2020, at 11:21 AM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Our web materials are live, unfortunately, we are still (b)(5) We have to get our PR out asap. Can we please (b)(5)

**Stephanie Caccomo**

*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.348.1256  
Cell: (b)(6)  
stephanie.caccomo@fda.hhs.gov

---

**From:** POLITICO Pro <politicoemail@politicopro.com>  
**Sent:** Monday, June 15, 2020 11:20 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

The Food and Drug Administration has withdrawn emergency use authorizations for two controversial coronavirus treatments promoted by President Donald Trump, amid concerns about their safety and effectiveness.

The drugs, hydroxychloroquine and chloroquine, have failed in several recent clinical trials, and doctors say they can cause serious heart problems. The FDA had allowed their use in hospitalized Covid-19 patients and in clinical trials.

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---

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---

**From:** Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]  
**Sent:** 6/15/2020 11:24:51 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(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:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, June 15, 2020 11:24 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** Fwd: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

Are we close!!!

Sent from my iPhone

Begin forwarded message:

**From:** "Caccomo, Stephanie" <Stephanie.Caccomo@fda.hhs.gov>  
**Date:** June 15, 2020 at 11:21:52 AM EDT  
**To:** "Caputo, Michael R (OS)" <Michael.Caputo@hhs.gov>  
**Cc:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Caligui, Laura" <Laura.Caligui@fda.hhs.gov>  
**Subject:** FW: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

Our web materials are live, unfortunately, we are still (b)(5) We have to get our PR out asap. Can we please (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:** POLITICO Pro <politicoemail@politicopro.com>  
**Sent:** Monday, June 15, 2020 11:20 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

The Food and Drug Administration has withdrawn emergency use authorizations for two controversial coronavirus treatments promoted by President Donald Trump, amid concerns about their safety and effectiveness.

The drugs, hydroxychloroquine and chloroquine, have failed in several recent clinical trials, and doctors say they can cause serious heart problems. The FDA had allowed their use in hospitalized Covid-19 patients and in clinical trials.

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---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 6/15/2020 11:52:10 AM  
**To:** Caputo, Michael R (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dac6080dfebe436da01db07986b63377-HHS-Michael]  
**CC:** Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Twomey, John K (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dabd734e611a472d826cd89d9bc4a352-HHS-John.Tw]; Paden, Maris (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9e96a29c69e547b9b26163f0e0db4dad-HHS-Maris.P]; Pinson, Alexander (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86ecb96fc7294239b8b3d077ed5d219c-HHS-Alexand]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]  
**Subject:** Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

We will track down and fix going forward.

Sent from my iPhone

On Jun 15, 2020, at 11:50 AM, Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov> wrote:

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:47 AM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

There are no unethical leakers. The letter and memo posted on the website

(b)(5)

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:35 AM, Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov> wrote:

+ Keagan

---

**From:** Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>

**Sent:** Monday, June 15, 2020 11:32 AM

**To:** Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>

**Cc:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>

**Subject:** Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

+Dr Hahn

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:29 AM, Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov> wrote:

+Alex

Agree with Sarah.

---

**From:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>

**Sent:** Monday, June 15, 2020 11:29 AM

**To:** Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>

**Subject:** RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

---

**From:** Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>

**Sent:** Monday, June 15, 2020 11:26 AM

**To:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>

**Subject:** RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

---

**From:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>

**Sent:** Monday, June 15, 2020 11:23 AM

**To:** Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>

**Subject:** Fwd: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

Begin forwarded message:

**From:** POLITICO Pro <politicoemail@politicopro.com>

**Date:** June 15, 2020 at 11:20:27 AM EDT

**To:** "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>

**Subject:** POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

**Reply-To:** "POLITICO, LLC" <reply-fe881c767362047b72-1158184 HTML-789053134-1376319-0@politicoemail.com>

The Food and Drug Administration has withdrawn emergency use authorizations for two controversial coronavirus treatments promoted by President Donald Trump, amid concerns about their safety and effectiveness.

The drugs, hydroxychloroquine and chloroquine, have failed in several recent clinical trials, and doctors say they can cause serious heart problems. The FDA had allowed their use in hospitalized Covid-19 patients and in clinical trials.

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This email was sent to sarah.arbes@hhs.gov by: POLITICO, LLC 1000 Wilson Blvd. Arlington, VA, 22209, USA



---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 6/15/2020 12:13:43 PM  
**To:** Caliguir, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**CC:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**Subject:** Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

He is furious. Why couldn't we hold till the Comms were ready?

Are we almost done? We need this out ASAP!

Sent from my iPhone

On Jun 15, 2020, at 12:12 PM, Caliguir, Laura <Laura.Caliguir@fda.hhs.gov> wrote:

10:55 this am to be clear. We need to get clarity for our team that once cleared and sent to ASPA, pens down. We were getting edits last night and make clear to ASPA that we have a robust clearance process as a regulatory agency and that we often need to use statutory language/legal. We need to solve for this on several sides.

---

**From:** Caliguir, Laura  
**Sent:** Monday, June 15, 2020 12:08 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

We do not hold regulatory actions for press. In addition to the evolving edits over the weekend, and ASPA/ Paul Alexander's edits came in at 10:55am.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, June 15, 2020 12:05 PM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Cc:** Caliguir, Laura <Laura.Caliguir@fda.hhs.gov>  
**Subject:** Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

But PR wasn't ready. Why wouldn't we wait till it was ready?

Sent from my iPhone

On Jun 15, 2020, at 11:53 AM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

The web content went live first, as is normal policy. We would have been ready as soon as web content live but for HHS edits.

Someone had politico tee'd up so that as soon as web content live, they could hit send on news.

**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 <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, June 15, 2020 11:52 AM  
**To:** Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** Fwd: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

How was this posted before PR was ready??

Sent from my iPhone

Begin forwarded message:

**From:** "Caputo, Michael (HHS/ASPA)" <Michael.Caputo@hhs.gov>  
**Date:** June 15, 2020 at 11:50:31 AM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** "Arbes, Sarah C (OS)" <Sarah.Arbes@hhs.gov>, "Shuy, Caitrin (OS)" <Caitrin.Shuy@hhs.gov>, "Hahn, Stephen" <SH1@fda.hhs.gov>, "Murphy, Ryan (OS)" <Ryan.Murphy1@hhs.gov>, "Pence, Laura (OS)" <Laura.Pence@hhs.gov>, "Oakley, Caitlin B (OS)" <Caitlin.Oakley@HHS.GOV>, "Morse, Sara N (OS)" <Sara.Morse@hhs.gov>, "Twomey, John K (OS)" <John.Twomey@HHS.GOV>, "Paden, Maris (OS)" <Maris.Paden@hhs.gov>, "Pinson, Alexander (OS)" <Alexander.Pinson@hhs.gov>, "Gross, Karas" <Karas.Gross@fda.hhs.gov>  
**Subject: Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine**

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:47 AM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

There are no unethical leakers. The letter and memo posted on the website: (b)(5)

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:35 AM, Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov> wrote:

+ Keagan

---

**From:** Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>

**Sent:** Monday, June 15, 2020 11:32 AM

**To:** Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; SH1 (fda.hhs.gov) <SH1@fda.hhs.gov>

**Cc:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Pinson, Alexander (HHS/ASFR) <Alexander.Pinson@hhs.gov>

**Subject:** Re: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

+Dr Hahn

(b)(5)

Sent from my iPhone

On Jun 15, 2020, at 11:29 AM, Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov> wrote:

+Alex

Agree with Sarah.

---

**From:** Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>

**Sent:** Monday, June 15, 2020 11:29 AM

**To:** Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>; Caputo, Michael (HHS/ASPA) <Michael.Caputo@hhs.gov>

**Subject:** RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

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**Subject:** RE: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

(b)(5)

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**Sent:** Monday, June 15, 2020 11:23 AM

**To:** Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Oakley,

Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Twomey, John K. (HHS/ASL) <John.Twomey@HHS.GOV>; Paden, Maris (HHS/ASL) <Maris.Paden@hhs.gov>

**Subject:** Fwd: POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

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Begin forwarded message:

**From:** POLITICO Pro <politicoemail@politicopro.com>

**Date:** June 15, 2020 at 11:20:27 AM EDT

**To:** "Arbes, Sarah (HHS/ASL)" <Sarah.Arbes@hhs.gov>

**Subject:** POLITICO Pro Breaking News: FDA ends emergency use of hydroxychloroquine

**Reply-To:** "POLITICO, LLC" <reply-fe881c767362047b72-1158184 HTML-789053134-1376319-0@politicoemail.com>

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 6/15/2020 12:43:10 PM  
**To:** Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]  
**Subject:** [REDACTED]  
**Attachments:** [REDACTED]

(b)(5)

Sent from my iPhone

Begin forwarded message:

**From:** "Robinson, Wilma (HHS/IOS)" <Wilma.Robinson@hhs.gov>  
**Date:** June 15, 2020 at 11:25:22 AM EDT  
**To:** OS - ASPA - Opioids <OS-ASPA-Opioids@hhs.gov>, "Moughalian, Jen C (OS)" <Jen.Moughalian@hhs.gov>, "Hayes, Jonathan H (OS)" <Jonathan.Hayes@hhs.gov>, "Shuy, Bryan (OS)" <Bryan.Shuy@hhs.gov>, "Waters, Cicely (OS)" <Cicely.Waters@hhs.gov>, "block.molly@epa.gov" <block.molly@epa.gov>, "Michael, Gretchen (OS)" <Gretchen.Michael@hhs.gov>, "Arbes, Sarah C (OS)" <Sarah.Arbes@hhs.gov>, "Morse, Sara N (OS)" <Sara.Morse@hhs.gov>, "Pence, Laura (OS)" <Laura.Pence@hhs.gov>, "Galatas, Kate (CDC)" <kkg2@cdc.gov>, CDC IMS JIC OADC LNO -2 <eocevent202@cdc.gov>, "Bonds, Michelle E (CDC)" <meb0@cdc.gov>, "Heldman, Amy B (CDC)" <evd4@cdc.gov>, "McGowan, Robert K (CDC)" <omc2@cdc.gov>, "Oury, Rachael (CDC)" <qkc3@cdc.gov>, "Brandt, Kimberly (CMS)" <Kimberly.Brandt1@cms.hhs.gov>, "Brookes, Brady (CMS)" <Brady.Brookes@cms.hhs.gov>, "Corry, Thomas (CMS)" <Thomas.Corry@cms.hhs.gov>, "Bell, Damian (CMS)" <Damian.Bell@cms.hhs.gov>, "Brady, William (OS)" <William.Brady@hhs.gov>, "Callahan, Kenneth (OS)" <Kenneth.Callahan@hhs.gov>, "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>, "Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>, "Caccommo, Stephanie" <Stephanie.Caccommo@fda.hhs.gov>, "Trueman, Laura (OS)" <Laura.Trueman@hhs.gov>, "Johnston, Darcie (OS)" <Darcie.Johnston@hhs.gov>, "Stannard, Paula (OS)" <Paula.Stannard@hhs.gov>, "Conrad, Patricia L (NIH)" <conradpa@niaid.nih.gov>, "Stover, Kathy A (NIH)" <kathy.stover@nih.gov>, "Routh, Jennifer M (NIH)" <jennifer.routh@nih.gov>, "Sherman, Jennifer (OS)" <Jennifer.Sherman@hhs.gov>, "Giroir, Brett (OS)" <Brett.Giroir@hhs.gov>, "Kellogg, Rachel (OS)" <Rachel.Kellogg@hhs.gov>, "Grigsby, Garrett G (OS)" <Garrett.Grigsby@hhs.gov>, "Stimson, Brian (OS)" <Brian.Stimson@hhs.gov>, "Charrow, Robert (OS)" <Robert.Charrow@hhs.gov>, "Thomas, Gloria D (OS)" <Gloria.Thomas@hhs.gov>, "Fulmer, Brendan (OS)" <Brendan.Fulmer@hhs.gov>, "Ezernack, Paige (OS)" <Paige.Ezernack@hhs.gov>, "Myles, Renate H (NIH)" <mylesr@mail.nih.gov>, "Burklow, John T (NIH)" <burklowj@od.nih.gov>, "Fine, Amanda B (NIH)" <amanda.fine@nih.gov>, "Fritz, Craig M (NIH)" <craig.fritz@nih.gov>, "Wojtowicz, Emma M (NIH)" <emma.wojtowicz@nih.gov>, "Akinso, Woleola O (NIH)" <akinsow@od.nih.gov>, "Beckham, Tammy (OS)" <Tammy.Beckham@hhs.gov>, "Monroe, Johnathan (CMS)" <Johnathan.Monroe1@cms.hhs.gov>, "Overstreet, Elizabeth (OS)" <Elizabeth.Overstreet@hhs.gov>, "Amin, John (OS)" <John.Amin@hhs.gov>, "Parker, Jim (OS)" <Jim.Parker@hhs.gov>, "Fetalvo, Ninio (CMS)" <Ninio.Fetalvo@cms.hhs.gov>, "Keveney, Sean (OS)" <Sean.Keveney@hhs.gov>, "Schwartz, Erica (OS)" <Erica.Schwartz@hhs.gov>, "Uehlecke, Nicholas (OS)" <Nicholas.Uehlecke@hhs.gov>, "Brooks, John (CMS)" <John.Brooks@cms.hhs.gov>, "Steele, Danielle (OS)" <Danielle.Steele@hhs.gov>, "Medler, Natalie (HHS/ASFR) (CTR)" <Natalie.Medler@hhs.gov>, "Robinson, Wilma (OS)" <Wilma.Robinson@hhs.gov>, "Bird, Catherine (OS)" <Catherine.Bird@hhs.gov>, "Agnew, Ann (OS)" <Ann.Agnew@hhs.gov>, "Mango, Paul (OS)" <Paul.Mango@hhs.gov>, "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>  
**Cc:** "Harrison, Brian (OS)" <Brian.Harrison@hhs.gov>, "Stecker, Judy (OS)" <Judy.Stecker@hhs.gov>, "Bird, Catherine (OS)" <Catherine.Bird@hhs.gov>, "Mango, Paul (OS)" <Paul.Mango@hhs.gov>, "Agnew, Ann (OS)" <Ann.Agnew@hhs.gov>  
**Subject:** FW: FOR REVIEW

(b)(5)

Wilma M. Robinson, PhD, MPH

Deputy Executive Secretary

Affirmative clearance is requested from **HRSA, SAMHSA, HIS and CMS**. Others are welcome to comment. Please send feedback to me **by COB today (6/15/2020)**

200 Independence Ave. SW  
Suite 603

Washington DC 20201

Office Phone: 202-690-5627

Office Cell: (b)(6)

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 6/22/2020 7:09:34 AM  
**To:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]  
**Subject:** Re: Therapeutics TPs for govts call tomorrow

Thx Michael!

Sent from my iPhone

On Jun 21, 2020, at 9:11 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi Patrick,

Yes, you can certainly use the information below. In addition, I'm sharing a couple of additional talkers on both therapeutics and vaccines below if you want to pull together something more comprehensive.

**(b)(5)**

There may be some additional talkers on the latest out of Operation Warp Speed.

Let us know if you need anything else!

Michael

Therapeutics:

**(b)(5)**

(b)(5)

---

**From:** Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>  
**Date:** June 21, 2020 at 8:38:27 PM EDT  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Cc:** Pence, Laura (OS) <Laura.Pence@hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>  
**Subject:** Therapeutics TPs for govcs call tomorrow

Hi FDA folks,

(b)(5)

Thank you!

- Patrick

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Friday, June 19, 2020 12:38 PM  
**To:** 'Kayleigh.McEnany@who.eop.gov' <Kayleigh.McEnany@who.eop.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** FDA adds for briefing remarks

Hi Kayleigh,

Sharing back some adds from FDA given it looks like the presser is at 1. Our team is checking on more specific survival benefit numbers and will circle back if we can share before then.



**REMARKS (new info from FDA highlighted)**

**(b)(5)**

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

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Brennan, Patrick (OS/ASPA) [Patrick.Brennan@hhs.gov]  
**Sent:** 6/22/2020 7:40:37 AM  
**To:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Caccamo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**CC:** Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** RE: Therapeutics TPs for gov's call tomorrow

Excellent, thank you, Michael!

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Sunday, June 21, 2020 9:12 PM  
**To:** Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>; Caccamo, Stephanie (FDA/OC) <Stephanie.Caccamo@fda.hhs.gov>  
**Cc:** Pence, Laura (HHS/IOS) <Laura.Pence@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>  
**Subject:** Re: Therapeutics TPs for gov's call tomorrow

Hi Patrick,

Yes, you can certainly use the information below. In addition, I'm sharing a couple of additional talkers on both therapeutics and vaccines below if you want to pull together something more comprehensive.

(b)(5)

There may be some additional talkers on the latest out of Operation Warp Speed.

Let us know if you need anything else!

Michael

(b)(5)

(b)(5)

---

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**Date:** June 21, 2020 at 8:38:27 PM EDT  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Cc:** Pence, Laura (OS) <Laura.Pence@hhs.gov>, Steele, Danielle (OS) <Danielle.Steele@hhs.gov>  
**Subject:** Therapeutics TPs for govts call tomorrow

Hi FDA folks,

(b)(5)

Thank you!

- Patrick

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**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** FDA adds for briefing remarks

Hi Kayleigh,

Sharing back some adds from FDA given it looks like the presser is at 1. Our team is checking on more specific survival benefit numbers and will circle back if we can share before then.

**REMARKS (new info from FDA highlighted)**

**(b)(5)**

Thanks,

Michael

**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

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 6/22/2020 8:46:11 AM  
**To:** Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]  
**Subject:** Re: Therapeutics TPs for govts call tomorrow

Thx.

Sent from my iPhone

On Jun 22, 2020, at 8:43 AM, Guram, Jeet <Jeet.Guram@fda.hhs.gov> wrote:

Hi Keagan, I think that covers it for dexamethasone and convalescent plasma, but he could say a bit more on remdesivir – here are some TPs:

(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](mailto:jeet.guram@fda.hhs.gov)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, June 22, 2020 7:08 AM  
**To:** Guram, Jeet <Jeet.Guram@fda.hhs.gov>  
**Subject:** Re: Therapeutics TPs for govts call tomorrow

Jeet- anything else the Secretary could be using today?

Sent from my iPhone

On Jun 21, 2020, at 8:38 PM, Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov> wrote:

Hi FDA folks,

(b)(5)

**(b)(5)**

Thank you!

- Patrick

---

**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>

**Sent:** Friday, June 19, 2020 12:38 PM

**To:** 'Kayleigh.McEnany@who.eop.gov' <Kayleigh.McEnany@who.eop.gov>

**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

**Subject:** FDA adds for briefing remarks

Hi Kayleigh,

Sharing back some adds from FDA given it looks like the presser is at 1. Our team is checking on more specific survival benefit numbers and will circle back if we can share before then.

**REMARKS (new info from FDA highlighted)**

**(b)(5)**

Thanks,

Michael

**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

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/23/2020 7:48:30 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniel]  
**Subject:** 113\_CovidVitals\_23 JUNE 2020.docx  
**Attachments:** 113\_CovidVitals\_23 JUNE 2020.docx; ATT00001.txt

Vitals for today.

---

**From:** Schiller, Lowell [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=77949B06919E4F91AA788E9A616C50C7-LOWELL.SCHI]  
**Sent:** 6/24/2020 2:23:34 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]  
**Subject:** TPs on OTMP paper  
**Attachments:** Talkers re OTMP paper.docx

INTERNAL DRAFT, DELIBERATIVE, PRE-DECISIONAL, CONFIDENTIAL

Keagan,

As discussed, attached are the draft talking points you requested regarding the OTMP paper.

Lowell

**Lowell J. Schiller**

*Principal Associate Commissioner for Policy*

Office of Policy

U.S. Food and Drug Administration

[lowell.schiller@fda.hhs.gov](mailto:lowell.schiller@fda.hhs.gov)



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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/24/2020 8:53:33 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 114\_CovidVitals\_24 JUNE 2020.docx  
**Attachments:** 114\_CovidVitals\_24 JUNE 2020.docx; ATT00001.txt

FDA Vitals for today

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/26/2020 6:37:38 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniel]  
**Subject:** 116\_CovidVitals\_26 JUNE 2020.docx  
**Attachments:** 116\_CovidVitals\_26 JUNE 2020.docx; ATT00001.txt

FDA Vitals Today.

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/29/2020 10:05:36 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 117\_CovidVitals\_29 JUNE 2020.docx  
**Attachments:** 117\_CovidVitals\_29 JUNE 2020.docx; ATT00001.txt

Vitals for today.

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 6/30/2020 10:43:11 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniel]  
**Subject:** 118\_CovidVitals\_30 JUNE 2020.docx  
**Attachments:** 118\_CovidVitals\_30 JUNE 2020.docx; ATT00001.txt

FDA Vitals Today.

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/6/2020 8:07:18 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]  
**Subject:** 121\_CovidVitals\_06 July 2020.docx  
**Attachments:** 121\_CovidVitals\_06 July 2020.docx; ATT00001.txt

vitals today



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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/7/2020 6:32:49 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 122\_CovidVitals\_07 July 2020.docx  
**Attachments:** 122\_CovidVitals\_07 July 2020.docx; ATT00001.txt

Vitals today

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/8/2020 11:30:20 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

You ok doing this?

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight

the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/8/2020 12:07:28 PM  
**To:** 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]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

He's an appropriator—adding Maren.

Since he wants to talk about OWS, given our role;

(b)(5)

(b)(5)

---

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

**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

FYI- can we start working on getting this done?

Sent from my iPhone

Begin forwarded message:

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

**Date:** July 8, 2020 at 11:30:14 AM EDT

**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>

**Cc:** Steve Daines; (b)(6)

**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

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Best

Steve

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**From:** Steve Daines <(b)(6)>  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

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**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

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**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Helms Williams, Emily [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=873BE46F1B1A4D2B8DF3FE67137CBDC8-HELMSWILLIA]  
**Sent:** 7/8/2020 2:52:00 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]  
**CC:** Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 8, 2020 at 2:49:10 PM EDT  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 2:47 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

On stand by for the decision. Thanks.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, July 8, 2020 12:04 PM  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

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Since he wants to talk about OWS, given our role

(b)(5)

(b)(5)

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**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

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Sent from my iPhone

Begin forwarded message:

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

**Date:** July 8, 2020 at 11:30:14 AM EDT

**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>

**Cc:** Steve Daines (b)(6)

**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

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Steve

---

**From:** Steve Daines (b)(6)

**Date:** July 8, 2020 at 9:06:05 AM MDT

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Subject:** Virtual Roundtable event with Senator Daines

**Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**



**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, [Caitlin\\_Affolter@daines.senate.gov](mailto:Caitlin_Affolter@daines.senate.gov), 202-774-8222

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**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/9/2020 10:47:16 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Happy to put something together.

Sent from my iPhone

On Jul 9, 2020, at 10:25 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

If this is considered a campaign event, then I can't do it. My understanding is that there will be press present. (b)(5)

(b)(5)

Thanks  
Steve

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Wednesday, July 8, 2020 at 2:33 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: Virtual Roundtable event with Senator Daines

See below from OGC:

(b)(5)

(b)(5)

Sent from my iPhone

Begin forwarded message:

**From:** "Helms Williams, Emily" <Emily.HelmsWilliams@fda.hhs.gov>  
**Date:** July 8, 2020 at 4:31:09 PM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Goldie, Christina" <Christina.Goldie@fda.hhs.gov>  
**Cc:** "Gross, Karas" <Karas.Gross@fda.hhs.gov>, "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Abram, Anna" <Anna.Abram@fda.hhs.gov>, "McBride, Maren" <Maren.McBride@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

I understand from HHS/OGC

(b)(5)

(b)(5)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, July 8, 2020 2:49 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna

<Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 2:47 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

On stand by for the decision. Thanks.

---

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

**Sent:** Wednesday, July 8, 2020 12:04 PM

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

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

He's an appropriator—adding Maren.

Since he wants to talk about OWS, given our role

(b)(5)

(b)(5)

---

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

**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

FYI- can we start working on getting this done?

Sent from my iPhone

Begin forwarded message:

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

**Date:** July 8, 2020 at 11:30:14 AM EDT

To: "Hahn, Stephen" <SH1@fda.hhs.gov>  
Cc: Steve Daines (b)(6)  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/9/2020 11:22:25 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

How is this:

(b)(5)

Sent from my iPhone

On Jul 9, 2020, at 10:25 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

If this is considered a campaign event, then I can't do it. My understanding is that there will be press present.

(b)(5)

(b)(5)

Thanks  
Steve

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Wednesday, July 8, 2020 at 2:33 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

Begin forwarded message:

**From:** "Helms Williams, Emily" <Emily.HelmsWilliams@fda.hhs.gov>  
**Date:** July 8, 2020 at 4:31:09 PM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>, "Goldie, Christina" <Christina.Goldie@fda.hhs.gov>  
**Cc:** "Gross, Karas" <Karas.Gross@fda.hhs.gov>, "Sheehy, Janice" <Janice.Sheehy@fda.hhs.gov>, "Abram, Anna" <Anna.Abram@fda.hhs.gov>, "McBride, Maren" <Maren.McBride@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

I understand from HHS/OGC

(b)(5)

(b)(5)

---

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

**Sent:** Wednesday, July 8, 2020 2:49 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>

**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna

<Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 2:47 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

On stand by for the decision. Thanks.

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**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Abram, Anna

<Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

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(b)(5)

Sent from my iPhone

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(b)(5)

(b)(5)

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<Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

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Sent from my iPhone

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**From:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
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**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Cc:** Steve Daines; (b)(6)  
**Subject:** Re: **Virtual Roundtable event with Senator Daines**

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

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**From:** Steve Daines; (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222



**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 7/9/2020 3:54:38 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Received. Thanks.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Thursday, July 9, 2020 3:54 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Hold pls. (b)(5)

Sent from my iPhone

On Jul 9, 2020, at 3:42 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

Hi all,

What is our plan for this request? Are we passing or moving forward? Thanks.

Best regards,

Chrisy

301-796-6833

---

**From:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Sent:** Wednesday, July 8, 2020 4:31 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

I understand from HHS/OGC

(b)(5)

(b)(5)

(b)(5)

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

**Sent:** Wednesday, July 8, 2020 2:49 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>

**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

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**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

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(b)(5)

(b)(5)

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**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

FYI- can we start working on getting this done?

Sent from my iPhone

Begin forwarded message:

**From:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 8, 2020 at 11:30:14 AM EDT  
**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Cc:** Steve Daines (b)(6)  
**Subject:** Re: Virtual Roundtable event with Senator Daines

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On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

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Best  
Steve

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**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

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**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Hoffman, Allison [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BEED30BE6A004DD29AC6C7F8EBCADBC5-ALLISON.HOF]  
**Sent:** 7/10/2020 11:21:10 AM  
**To:** Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; 'Affolter, Caitlin (Daines)' [Caitlin\_Affolter@daines.senate.gov]; Schoettler, Katie (Daines) [Katie\_Schoettler@daines.senate.gov]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Thacker, Darin (Daines) [Darin\_Thacker@daines.senate.gov]; Thielman, Jason (Daines) [Jason\_Thielman@daines.senate.gov]; Green, Rachel (Daines) [Rachel\_Green@daines.senate.gov]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; Nguyen, Mimi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=806b10ea0d144541b48beed0b5e35796-Mimi.Nguyen]; Hoffman, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=beed30be6a004dd29ac6c7f8ebcadbc5-Allison.Hof]; Franklin, Joseph [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

+Mimi Nguyen

Adding Mimi Nguyen (cc'd; [mimi.nguyen@fda.hhs.gov](mailto:mimi.nguyen@fda.hhs.gov)) – she is Dr. Abernethy's special assistant and handles logistics. I am the main contact for content.

Regards,  
Allison

---

**From:** Goldie, Christina <[Christina.Goldie@fda.hhs.gov](mailto:Christina.Goldie@fda.hhs.gov)>  
**Sent:** Friday, July 10, 2020 11:19 AM  
**To:** 'Affolter, Caitlin (Daines)' <[Caitlin\\_Affolter@daines.senate.gov](mailto:Caitlin_Affolter@daines.senate.gov)>; Schoettler, Katie (Daines) <[Katie\\_Schoettler@daines.senate.gov](mailto:Katie_Schoettler@daines.senate.gov)>; Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>  
**Cc:** Thacker, Darin (Daines) <[Darin\\_Thacker@daines.senate.gov](mailto:Darin_Thacker@daines.senate.gov)>; Thielman, Jason (Daines) <[Jason\\_Thielman@daines.senate.gov](mailto:Jason_Thielman@daines.senate.gov)>; Green, Rachel (Daines) <[Rachel\\_Green@daines.senate.gov](mailto:Rachel_Green@daines.senate.gov)>; Sheehy, Janice <[Janice.Sheehy@fda.hhs.gov](mailto:Janice.Sheehy@fda.hhs.gov)>; McBride, Maren <[Maren.McBride@fda.hhs.gov](mailto:Maren.McBride@fda.hhs.gov)>; Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>; Hoffman, Allison <[Allison.Hoffman@fda.hhs.gov](mailto:Allison.Hoffman@fda.hhs.gov)>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event.

[Allison.hoffman@fda.hhs.gov](mailto:Allison.hoffman@fda.hhs.gov) I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**  
*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: 301-796-6833 / Main office 301-796-5000  
[Christina.Goldie@fda.hhs.gov](mailto:Christina.Goldie@fda.hhs.gov)



---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Friday, July 10, 2020 11:00 AM  
**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

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Best  
Steve

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**From:** Steve Daines <(b)(6)>  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes



**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

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**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/10/2020 2:39:55 PM  
**To:** Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Andrew.Caplan@HHS.GOV

---

**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:38 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Sure. Is there someone we work with over there, or should I ask OCC?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:37 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

(b)(5)

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**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

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**Subject:** RE: Virtual Roundtable event with Senator Daines

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(b)(5)

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**Sent:** Thursday, July 9, 2020 10:43 AM

**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

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Sent from my iPhone

On Jul 8, 2020, at 4:31 PM, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov> wrote:

I understand from HHS/OGC

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(b)(5)

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**Subject:** Re: Virtual Roundtable event with Senator Daines

Also, he is up for re-election so he would like to make sure we aren't running a foul the HATCH Act. Can you run that down too?

He would like to help, but maybe it makes more sense for HHS to do?

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

He's an appropriator—adding Maren.

Since he wants to talk about OWS, given our role, would it make more sense to work with HHS to offer another HHS principal or does Dr. Hahn want to do it regardless?

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

**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

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**Cc:** Steve Daines <sddaines@aol.com>

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**Date:** July 8, 2020 at 9:06:05 AM MDT

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Subject:** Virtual Roundtable event with Senator Daines

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**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

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**Sent:** 7/10/2020 2:56:57 PM  
**To:** Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Adding Jim

Sent from my iPhone

On Jul 10, 2020, at 2:48 PM, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov> wrote:

I will find out.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 10, 2020 at 2:28:49 PM EDT  
**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

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**Subject:** Virtual Roundtable event with Senator Daines

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**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual



**Date of the Event:** Week of July 13th -- 30 minutes

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**Sent:** 7/10/2020 3:01:44 PM  
**To:** Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]  
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**Subject:** Re: Virtual Roundtable event with Senator Daines

Would have to check with Asim for Anand I think.

Sent from my iPhone

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(b)(5)

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**To:** Caplan, Andrew (OS) <Andrew.Caplan@HHS.GOV>  
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(b)(5)

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**James Flahive, JD**  
*Senior Advisor, Office of the Chief of Staff*

Office of the Commissioner  
U.S. Food and Drug Administration  
Desk 301-796-9293 | Cell: (b)(6)  
james.flahive@fda.hhs.gov

<image001.png>

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**Subject:** Re: Virtual Roundtable event with Senator Daines

Thanks Jim, I will give you a call shortly.

---

**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Date:** July 10, 2020 at 2:58:59 PM EDT  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
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(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

He's an appropriator—adding Maren.

Since he wants to talk about OWS, given our role,

(b)(5)

(b)(5)

---

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

**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

FYI- can we start working on getting this done?

Sent from my iPhone

Begin forwarded message:

**From:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 8, 2020 at 11:30:14 AM EDT  
**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Cc:** Steve Daines; (b)(6)  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines; (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/11/2020 3:14:42 PM  
**To:** McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** Fwd: Virtual Roundtable event with Senator Daines

Sent from my iPhone

Begin forwarded message:

**From:** "Flahive, James" <James.Flahive@fda.hhs.gov>  
**Date:** July 11, 2020 at 10:34:27 AM EDT  
**To:** "Caplan, Andrew (OS)" <Andrew.Caplan@HHS.GOV>  
**Cc:** "Helms Williams, Emily" <Emily.HelmsWilliams@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Thank you, Andy!  
We appreciate this!

---

**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Date:** July 10, 2020 at 7:30:30 PM EDT  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

(b)(5)

Thank you very much.”

Please let me know if you need any further assistance.

Andy

Andy Caplan

Senior Ethics Counsel

Office of the General Counsel

U.S. Dept. of Health & Human Services

(b)(6)

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**From:** Flahive, James <James.Flahive@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 6:33 PM

**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>

**Subject:** RE: Virtual Roundtable event with Senator Daines

Hi Andy,

I'm waiting for Keagan to weigh in on this.

Sorry for the 11<sup>th</sup> hour request.

---

**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>

**Sent:** Friday, July 10, 2020 5:38 PM

**To:** Flahive, James <James.Flahive@fda.hhs.gov>

**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Andy

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**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 3:19 PM  
**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Cc:** Helms Williams, Emily (FDA/OC) <Emily.HelmsWilliams@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

Thanks, Andy.

Please let me know if you need more info than the below to (b)(5) or have follow up questions.

Jim

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 3:17 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Closed and open to some press. Not handled by campaign at all. No idea if there will be any donors, possible, but also something the office or campaign aren't tracking either.

Sent from my iPhone

On Jul 10, 2020, at 3:13 PM, Flahive, James <James.Flahive@fda.hhs.gov> wrote:

Hi Keagan,

If we still want to pursue, we need to answer the below questions for Andy Caplan. Let me know how you want to proceed.

**(b)(5)**

(b)(5)

Andy  
Andy Caplan  
Senior Ethics Counsel  
Office of the General Counsel  
U.S. Dept. of Health & Human Services

(b)(6)

---

**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Sent:** Friday, July 10, 2020 3:05 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Andy  
Andy Caplan  
Senior Ethics Counsel  
Office of the General Counsel  
U.S. Dept. of Health & Human Services

(b)(6)

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**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:50 PM  
**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Cc:** Helms Williams, Emily (FDA/OC) <Emily.HelmsWilliams@fda.hhs.gov>; McBride, Maren (FDA/OC) <Maren.McBride@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

Hi Andrew,

(b)(5)

Please feel free to give me a call if it would be helpful to discuss.

Thanks,  
Jim

**James Flahive, JD**  
*Senior Advisor, Office of the Chief of Staff*

Office of the Commissioner  
U.S. Food and Drug Administration  
Desk: 301-796-9293 | Cell: (b)(6)  
[james.flahive@fda.hhs.gov](mailto:james.flahive@fda.hhs.gov)

<image001.png>

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:37 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

(b)(5)

---

**From:** Lenihan, Keagan  
**Sent:** Friday, July 10, 2020 2:29 PM  
**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Sec Purdue did this event with the Senator a few weeks ago.

(b)(5)

(b)(5)

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**From:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Sent:** Thursday, July 9, 2020 11:01 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Sure, how's this –

Dear Senator Daines,

(b)(5)

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Thursday, July 9, 2020 10:43 AM  
**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines



(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 4:31 PM, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov> wrote:

I understand from HHS/OGC

(b)(5)

(b)(5)

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

**Sent:** Wednesday, July 8, 2020 2:49 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>

**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 2:47 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

On stand by for the decision. Thanks.

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

**Sent:** Wednesday, July 8, 2020 12:04 PM

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

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

He would like to help

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

He's an appropriator—adding Maren.

Since he wants to talk about OWS, given our role:

(b)(5)

(b)(5)

---

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

**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

FYI- can we start working on getting this done?

Sent from my iPhone

Begin forwarded message:

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

**Date:** July 8, 2020 at 11:30:14 AM EDT

**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>

**Cc:** Steve Daines (b)(6)

**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best

Steve

---

**From:** Steve Daines (b)(6)

**Date:** July 8, 2020 at 9:06:05 AM MDT

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Subject:** Virtual Roundtable event with Senator Daines

**Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

<mime-attachment>

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**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/11/2020 8:38:12 PM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Thanks.

Sent from my iPhone

On Jul 11, 2020, at 6:16 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

OK great and thanks.

(b)(5)

Steve

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Saturday, July 11, 2020 at 1:15 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: Virtual Roundtable event with Senator Daines

(b)(5)

Will have Maren work it out with their team.

Sent from my iPhone

Begin forwarded message:

**From:** "Flahive, James" <James.Flahive@fda.hhs.gov>  
**Date:** July 11, 2020 at 10:34:27 AM EDT  
**To:** "Caplan, Andrew (OS)" <Andrew.Caplan@HHS.GOV>  
**Cc:** "Helms Williams, Emily" <Emily.HelmsWilliams@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Thank you, Andy!  
We appreciate this!

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**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Date:** July 10, 2020 at 7:30:30 PM EDT  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

(b)(5)

Thank you very much.”

Please let me know if you need any further assistance.

Andy

Andy Caplan

Senior Ethics Counsel

Office of the General Counsel

U.S. Dept. of Health & Human Services

(b)(6)

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**From:** Flahive, James <James.Flahive@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 6:33 PM

**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>

**Subject:** RE: Virtual Roundtable event with Senator Daines

Hi Andy,

I'm waiting for Keagan to weigh in on this.

Sorry for the 11<sup>th</sup> hour request.

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**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Andy

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**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Cc:** Helms Williams, Emily (FDA/OC) <Emily.HelmsWilliams@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

Thanks, Andy.

Please let me know if you need more info than the below (b)(5) or have follow up questions.

Jim

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**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Closed and open to some press. Not handled by campaign at all. No idea if there will be any donors, possible, but also something the office or campaign aren't tracking either.

Sent from my iPhone

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Hi Keagan,

If we still want to pursue, we need to answer the below questions for Andy Caplan. Let me know how you want to proceed.

(b)(5)

Andy  
Andy Caplan  
Senior Ethics Counsel  
Office of the General Counsel  
U.S. Dept. of Health & Human Services  
(b)(6)

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**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Sent:** Friday, July 10, 2020 3:05 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Andy  
Andy Caplan  
Senior Ethics Counsel  
Office of the General Counsel  
U.S. Dept. of Health & Human Services  
(b)(6)

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---

**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:50 PM  
**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Cc:** Helms Williams, Emily (FDA/OC) <Emily.HelmsWilliams@fda.hhs.gov>; McBride, Maren (FDA/OC) <Maren.McBride@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

Hi Andrew,

(b)(5)

Please feel free to give me a call if it would be helpful to discuss.

Thanks,  
Jim

**James Flahive, JD**  
*Senior Advisor, Office of the Chief of Staff*  
  
Office of the Commissioner  
U.S. Food and Drug Administration  
Desk 301-796-9293 | Cell (b)(6)  
james.flahive@fda.hhs.gov

<image001.png>

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:37 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

(b)(5)

(b)(5)

---

**From:** Lenihan, Keagan  
**Sent:** Friday, July 10, 2020 2:29 PM  
**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Sec Purdue did this event with the Senator a few weeks ago.

(b)(5)

(b)(5)

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**Sent:** Thursday, July 9, 2020 11:01 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Sure, how's this –

Dear Senator Daines,



(b)(5)

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Thursday, July 9, 2020 10:43 AM  
**To:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 4:31 PM, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov> wrote:

I understand from HHS/OGC that this type of eve

(b)(5)

(b)(5)

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, July 8, 2020 2:49 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** Gross, Karas <Karas.Gross@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 2:47 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

On stand by for the decision. Thanks.

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, July 8, 2020 12:04 PM  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** Re: Virtual Roundtable event with Senator Daines

(b)(5)

He would like to help

(b)(5)

Sent from my iPhone

On Jul 8, 2020, at 11:59 AM, Gross, Karas <Karas.Gross@fda.hhs.gov> wrote:

He's an appropriator—adding Maren.

Since he wants to talk about OWS, given our role

(b)(5)

(b)(5)

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

**Date:** July 8, 2020 at 11:47:21 AM EDT

**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>

**Subject:** Fwd: Virtual Roundtable event with Senator Daines

FYI- can we start working on getting this done?

Sent from my iPhone

Begin forwarded message:

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

**Date:** July 8, 2020 at 11:30:14 AM EDT

**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>

**Cc:** Steve Daine (b)(6)

**Subject:** Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best

Steve

---

**From:** Steve Daines

(b)(6)

**Date:** July 8, 2020 at 9:06:05 AM MDT

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

<mime-attachment>

---

**From:** McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]  
**Sent:** 7/12/2020 12:52:03 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: Virtual Roundtable event with Senator Daines

Yep

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 11, 2020 at 8:38:44 PM EDT  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Subject:** Fwd: Virtual Roundtable event with Senator Daines

Can you pls organize and work this out between Janice and Daines team?

Sent from my iPhone

Begin forwarded message:

**From:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Date:** July 11, 2020 at 6:16:07 PM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: **Virtual Roundtable event with Senator Daines**

OK great and thanks.

(b)(5)

Steve

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Saturday, July 11, 2020 at 1:15 PM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** Fwd: Virtual Roundtable event with Senator Daines

(b)(5)

Will have Maren work it out with their team.

Sent from my iPhone

Begin forwarded message:

**From:** "Flahive, James" <James.Flahive@fda.hhs.gov>  
**Date:** July 11, 2020 at 10:34:27 AM EDT  
**To:** "Caplan, Andrew (OS)" <Andrew.Caplan@HHS.GOV>  
**Cc:** "Helms Williams, Emily" <Emily.HelmsWilliams@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: **Virtual Roundtable event with Senator Daines**

Thank you, Andy!  
We appreciate this!

**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>

**Date:** July 10, 2020 at 7:30:30 PM EDT

**To:** Flahive, James <James.Flahive@fda.hhs.gov>

**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Thank you very much.”

Please let me know if you need any further assistance.

Andy

Andy Caplan

Senior Ethics Counsel

Office of the General Counsel

U.S. Dept. of Health & Human Services

(b)(6)

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**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 6:33 PM  
**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

Hi Andy,  
I'm waiting for Keagan to weigh in on this.

Sorry for the 11<sup>th</sup> hour request.

---

**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Sent:** Friday, July 10, 2020 5:38 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Andy

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**From:** Flahive, James <James.Flahive@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 3:19 PM  
**To:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>  
**Cc:** Helms Williams, Emily (FDA/OC) <Emily.HelmsWilliams@fda.hhs.gov>; Lenihan, Keagan (FDA/OC) <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Virtual Roundtable event with Senator Daines

Thanks, Andy.

Please let me know if you need more info than the below t: (b)(5) or have follow up questions.

Jim

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 3:17 PM  
**To:** Flahive, James <James.Flahive@fda.hhs.gov>

**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>

**Subject:** Re: Virtual Roundtable event with Senator Daines

Closed and open to some press. Not handled by campaign at all. No idea if there will be any donors, possible, but also something the office or campaign aren't tracking either.

Sent from my iPhone

On Jul 10, 2020, at 3:13 PM, Flahive, James <James.Flahive@fda.hhs.gov> wrote:

Hi Keagan,

If we still want to pursue, we need to answer the below questions for Andy Caplan. Let me know how you want to proceed.

(b)(5)

Andy  
Andy Caplan  
Senior Ethics Counsel  
Office of the General Counsel  
U.S. Dept. of Health & Human Services

(b)(6)

---

**From:** Caplan, Andrew (HHS/OGC) <Andrew.Caplan@HHS.GOV>

**Sent:** Friday, July 10, 2020 3:05 PM

**To:** Flahive, James <James.Flahive@fda.hhs.gov>

**Cc:** Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>

**Subject:** RE: Virtual Roundtable event with Senator Daines

(b)(5)

Andy

Andy Caplan  
Senior Ethics Counsel  
Office of the General Counsel  
U.S. Dept. of Health & Human Services

(b)(6)

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**Subject:** FW: Virtual Roundtable event with Senator Daines

Hi Andrew,

An ethics question

(b)(5)

(b)(5)

Please feel free to give me a call if it would be helpful to discuss.

Thanks,  
Jim

**James Flahive, JD**  
*Senior Advisor, Office of the Chief of Staff*

Office of the Commissioner  
U.S. Food and Drug Administration  
Desk 301-796-9293 | Cell: (b)(6)  
james.flahive@fda.hhs.gov

<image001.png>

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(b)(5)

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(b)(5)

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**To:** "Hahn, Stephen" <SH1@fda.hhs.gov>

**Cc:** Steve Daines (b)(6)

**Subject:** Re: Virtual Roundtable event with Senator Daines

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Best

Steve

---

**From:** Steve Daines

(b)(6)

**Date:** July 8, 2020 at 9:06:05 AM MDT

**To:** Hahn, Stephen <SH1@fda.hhs.gov>

**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

<mime-attachment>

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 7/13/2020 8:25:00 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** COVID Daily  
**Attachments:** COVID Daily 7.13.20.docx

Attached!

Let me know what else you think we might need!

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/13/2020 8:27:51 AM  
**To:** Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]  
**Subject:** 6D9C8C1A-1880-419B-97E9-42FCFE960F5A  
**Attachments:** COVID Daily 7.13.20.docx; ATT00001.txt

FDA update today. Sorry we won't be on the call.

---

**From:** McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]  
**Sent:** 7/13/2020 10:40:31 AM  
**To:** Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Chrisy- I'll circle back with you on next steps shortly. thx

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 9:18 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Okay, thanks Keagan.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 9:14 AM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

**(b)(5)** Pls work with Maren.

Sent from my iPhone

On Jul 13, 2020, at 9:01 AM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

Good morning,

I just wanted to see if we have any further information about this one.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:36 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>  
**Cc:** Thacker, Darin (Daines) <Darin.Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason.Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

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**Sent:** Friday, July 10, 2020 11:19 AM

**To:** 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event.

Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,



Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDAs Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines: (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** McBride, Maren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B65D2B38307F4B489E266D2178C46793-MAREN.KAHN]  
**Sent:** 7/13/2020 11:11:15 AM  
**To:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]  
**CC:** Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Earley, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05737f759eb54e9188cb16cbb467d12-Rosemary.Ea]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Janice—I'll check. I'm going to try and connect with his staff now and will circle back!

---

**From:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 9:18 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Cc:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

This is for 4pm ET on Thursday, July 16<sup>th</sup>. (b)(6) Is Maren to ask for another option or (b)(6)  
(b)(6) ?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 9:14 AM  
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**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(5) Pls work with Maren.

Sent from my iPhone

On Jul 13, 2020, at 9:01 AM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

Good morning,  
I just wanted to see if we have any further information about this one.

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**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

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**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event.

Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: 301-796-6833 / Main office 301-796-5000  
Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

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We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
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**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

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We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

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Best  
Steve

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**From:** Steve Daines <(b)(6)>  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

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**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.



---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/13/2020 9:37:49 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 126\_CovidVitals\_13 July 2020.docx  
**Attachments:** 126\_CovidVitals\_13 July 2020.docx; ATT00001.txt

FDA Vitals

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/14/2020 9:42:33 AM  
**To:** McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**CC:** Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Earley, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05737f759eb54e9188cb16cbb467d12-Rosemary.Ea]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

I will ask him.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Tuesday, July 14, 2020 8:31 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Cc:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(6)

If not, then I think we need to do Anand.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 14, 2020 at 8:16:47 AM EDT  
**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Flahive, James <James.Flahive@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

So, Maren he can't do it. Want Anand?

Sent from my iPhone

On Jul 14, 2020, at 8:14 AM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

That is correct.

---

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

**Date:** July 14, 2020 at 8:13:33 AM EDT

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Flahive, James <James.Flahive@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

I think (b)(6)

Sent from my iPhone

On Jul 14, 2020, at 8:09 AM, McBride, Maren <Maren.McBride@fda.hhs.gov> wrote:

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Janice, they aren't able to change the time due to the senator's travel this week so they'd really prefer to keep it for this Thursday at 4:00 EST.

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**From:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>

**Date:** July 13, 2020 at 9:18:18 AM EDT

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

This is for 4pm ET on Thursday, July 16<sup>th</sup>. (b)(6) Is Maren to ask for another option or is he going to (b)(6) to accommodate?

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**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(5) Pls work with Maren.

Sent from my iPhone

On Jul 13, 2020, at 9:01 AM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

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I just wanted to see if we have any further information about this one.

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

**Sent:** Friday, July 10, 2020 2:36 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

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**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

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Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice

<Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

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**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Sent:** Wednesday, July 8, 2020 1:09 PM

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

**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDAs Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines; (b)(6)  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines; (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/14/2020 11:46:01 AM  
**To:** McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]  
**Subject:** Fwd: Hi Keagan, Virtual Roundtable event with Senator Daines

See below. If they can't move pls get Anand.

Sent from my iPhone

Begin forwarded message:

**From:** "Hahn, Stephen" <SH1@fda.hhs.gov>  
**Date:** July 14, 2020 at 11:25:25 AM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Please and give them my apologies.  
Steve

(b)(6)

Could they move it up any time earlier?

---

**From:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** Tuesday, July 14, 2020 at 9:42 AM  
**To:** Stephen Hahn <SH1@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Daines office can't move the time of the event, but you will be (b)(6) Do you want Anand to handle?

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Tuesday, July 14, 2020 8:31 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Cc:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(6)

If not, then I think we need to do Anand.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 14, 2020 at 8:16:47 AM EDT  
**To:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Flahive, James <James.Flahive@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

So, Maren he can't do it. Want Anand?

Sent from my iPhone



On Jul 14, 2020, at 8:14 AM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

That is correct.

---

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

**Date:** July 14, 2020 at 8:13:33 AM EDT

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Goldie, Christina <Christina.Goldie@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Flahive, James <James.Flahive@fda.hhs.gov>

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I think he is (b)(6)

Sent from my iPhone

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<image006.jpg>

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**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
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**Sent:** Wednesday, July 8, 2020 1:09 PM  
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**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

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**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 7/14/2020 6:37:23 PM  
**To:** Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; 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]  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

fyi

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Tuesday, July 14, 2020 6:35 PM  
**To:** Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Janice and I just confirmed 2:30pm EDT next Wednesday, July 22nd for the updated time for the form! Thanks all!!

On Jul 14, 2020, at 5:56 PM, Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov> wrote:

Thanks, Maren. Attached is the completed event request form. Let me know if you have any questions or need additional information from me.

Rachel

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Tuesday, July 14, 2020 4:28 PM  
**To:** Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Rachel—thanks for chatting! We will get back to you on the participants, as well as some other date/times options as soon as I can connect with the Commissioner's scheduler.

Can you help us fill out the attached form?

Many thanks!

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 3:58 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Maren—below is a list of folks we intend to invite to the virtual roundtable. Please let us know if there is an issue with including Jay Evans, Director for the Center of Translational Medicine at UM.

- Scott Ellner – CEO of Billings Clinic
- Craig Lambrecht – CEO of Kalispell Regional Healthcare
- John Hill – President & CEO of Bozeman Health
- John Goodnow – CEO of Benefis Health System (Great Falls)
- Dr. Dean French – CEO of Community Medical Center (Missoula)
- Cherie Taylor – CEO of Northern Rockies Medical Center (Cut Bank)
- Laura Merchant – CEO of Liberty Medical Center (Chester)
- Maria Clemons – CEO of Northwest Montana Community Health Center (Libby, Troy)
- William Keifer – CEO of Marias Medical Center (b)(6) Toole County
- Jay Evans – Director for Center for Translational Medicine (UM)

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 2:42 PM

**To:** Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey can we chat quickly? Have a scheduling issue on our end. I'm at (b)(6)

---

**From:** Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 2:30 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Please find below the zoom information. Will you all have anyone else joining in addition to Dr. Hahn? We will send our attendees shortly. As mentioned, press will be on the zoom but on mute only.

caitlin\_affolter@daines.senate.gov is inviting you to a scheduled ZoomGov meeting.

Topic: Senator Daines, FDA Commissioner Hahn Virtual Roundtable on COVID-19 Vaccine, Update  
Time: Jul 16, 2020 04:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting

(b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

(b)(6)

US (San Jose)

US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

+1 646 828 7666 US (New York)

Meeting ID: (b)(6)

Password: (b)(6)

Find your local number (b)(6)

Join by SIP

(b)(6)

Join by H.323

(b)(6) (US West)  
(b)(6) (US East)

Meeting ID: (b)(6)  
Password: (b)(6)

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 4:06 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Guys—

Thanks so much for talking earlier. Commissioner Hahn is looking forward to discussing FDA's work related to COVID-19 vaccines with the Senator and other folks later this week at the Roundtable.

Given that this is an official event, the political activity restrictions in federal law including the Hatch Act will apply to the Commissioner's participation. As I mentioned on the phone, there are a few items listed below I was hoping I could get clarified on your end.

- Please confirm that this will be an official event for the Senator and not a campaign event.



- Please confirm that the Senator's costs associated with this event will be paid for with his official funds and not campaign funds and staffed only by official staff only (ie no campaign staff).
  - Please confirm that there will be no discussion or remarks related to the upcoming elections during the event and the Senator will be using official resources, including his Member's Representational Allowance (or comparable official budget funds).
  - Please confirm that any photos associated with the event may only be used for non-campaign related purposes.
- Also, when you guys know, can you please email us the names/titles of the other participants?
  - And finally, I have also cc'ed our communications POCs—Stephanie Cacommo and John Wagner—for you guys to connect.

Thanks much!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 12:42 PM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Invite coming shortly

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 12:04 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Confirmed for 1:30pm EDT. If you could send us a calendar invite that would be great. I have cc'd everyone from our crew that will be on the line.

Katie, Comms  
 Rachel, Health LA  
 Dan and Liz, MT state staff (who will discuss the invitees)  
 And me from scheduling 😊

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:56 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen,

Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Great. Does 1:30 work for you guys? Want to call me or should I send a call-in invite (if you both want to join)? Thanks!

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Monday, July 13, 2020 11:54 AM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

We are happy to chat! We are on our all staff call until 12:30pm EDT. Perhaps, sometime this early afternoon? We are flexible and very grateful for Dr. Hahn's time.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 11:22 AM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Adding the right email for Katie this time!

---

**From:** McBride, Maren

**Sent:** Monday, July 13, 2020 11:20 AM

**To:** Caitlin\_Affolter@daines.senate.gov; katie\_schoettler@damines.senate.gov

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Ladies—do you have few minutes to chat about this event this morning? I'm at (b)(6) if so. I'm trying to track down a few pieces of info, but I think it's likely Dr. Hahn will be able to participate once I can confirm a few things. Thank you

---

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

**Sent:** Friday, July 10, 2020 2:36 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 11:19 AM

**To:** 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event.

Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina

<Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,

Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Sent:** Wednesday, July 8, 2020 1:09 PM

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

**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDAs Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

<Commissioner External Event Request Form - Senator Daines Request.doc>

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 7/15/2020 2:41:31 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**CC:** Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Keagan,

Just looping you in. I saw the Q&A was not planned and wanted to make sure you knew that. Ok?

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Wednesday, July 15, 2020 2:10 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi—we got some TPs from Stephanie and Wolf and will use those so I think we are good on that front. We will also do a background/run of show memo to walk him through if that works for everyone?

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Sent:** Wednesday, July 15, 2020 1:00 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Thanks for sending this forward. Looks like we need some prepared remarks for about 5 minutes with 20 minutes Q&A from the group. Do we have a sense of the questions at all? I have cc'd Alex Wohl to coordinate the remarks for Dr. Hahn unless your office had plans to coordinate the remarks. Please let me know. Thanks.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: 301-796-6833 / Main office 301-796-5000  
Christina.Goldie@fda.hhs.gov



---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Wednesday, July 15, 2020 12:49 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen,

Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Attached is the form. I think we may need to update the date though since the event is now next Wednesday at 2:30.

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 5:56 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Thanks, Maren. Attached is the completed event request form. Let me know if you have any questions or need additional information from me.

Rachel

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 4:28 PM

**To:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Rachel—thanks for chatting! We will get back to you on the participants, as well as some other date/times options as soon as I can connect with the Commissioner's scheduler.

Can you help us fill out the attached form?

Many thanks!

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 3:58 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Maren—below is a list of folks we intend to invite to the virtual roundtable. Please let us know if there is an issue with including Jay Evans, Director for the Center of Translational Medicine at UM.

- Scott Ellner – CEO of Billings Clinic
- Craig Lambrecht – CEO of Kalispell Regional Healthcare



- John Hill – President & CEO of Bozeman Health
- John Goodnow – CEO of Benefis Health System (Great Falls)
- Dr. Dean French – CEO of Community Medical Center (Missoula)
- Cherie Taylor – CEO of Northern Rockies Medical Center (Cut Bank)
- Laura Merchant – CEO of Liberty Medical Center (Chester)
- Maria Clemons – CEO of Northwest Montana Community Health Center (Libby, Troy)
- William Keifer – CEO of Marias Medical Center: (b)(6) (Toole County)
- Jay Evans – Director for Center for Translational Medicine (UM)

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 2:42 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey can we chat quickly? Have a scheduling issue on our end. I'm at (b)(6)

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 2:30 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Please find below the zoom information. Will you all have anyone else joining in addition to Dr. Hahn? We will send our attendees shortly. As mentioned, press will be on the zoom but on mute only.

caitlin\_affolter@daines.senate.gov is inviting you to a scheduled ZoomGov meeting.

Topic: Senator Daines, FDA Commissioner Hahn Virtual Roundtable on COVID-19 Vaccine, Update  
Time: Jul 16, 2020 04:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting

(b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

(b)(6)

US (San Jose)

US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

+1 646 828 7666 US (New York)

Meeting ID: (b)(6)

Password: (b)(6)

Find your local number: (b)(6)

Join by SIP

(b)(6)

Join by H.323

(b)(6)

US West)

US East)

Meeting ID: (b)(6)

Password: (b)(6)

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 4:06 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Guys—

Thanks so much for talking earlier. Commissioner Hahn is looking forward to discussing FDA's work related to COVID-19 vaccines with the Senator and other folks later this week at the Roundtable.

Given that this is an official event, the political activity restrictions in federal law including the Hatch Act will apply to the Commissioner's participation. As I mentioned on the phone, there are a few items listed below I was hoping I could get clarified on your end.

- Please confirm that this will be an official event for the Senator and not a campaign event.
- Please confirm that the Senator's costs associated with this event will be paid for with his official funds and not campaign funds and staffed only by official staff only (ie no campaign staff).
- Please confirm that there will be no discussion or remarks related to the upcoming elections during the event and the Senator will be using official resources, including his Member's Representational Allowance (or comparable official budget funds).
- Please confirm that any photos associated with the event may only be used for non-campaign related purposes.
- Also, when you guys know, can you please email us the names/titles of the other participants?
- And finally, I have also cc'ed our communications POCs—Stephanie Caccomo and John Wagner—for you guys to connect.

Thanks much!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 12:42 PM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Invite coming shortly

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 12:04 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Confirmed for 1:30pm EDT. If you could send us a calendar invite that would be great. I have cc'd everyone from our crew that will be on the line.

Katie, Comms  
Rachel, Health LA  
Dan and Liz, MT state staff (who will discuss the invitees)  
And me from scheduling 😊

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:56 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Great. Does 1:30 work for you guys? Want to call me or should I send a call-in invite (if you both want to join)? Thanks!

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 11:54 AM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

We are happy to chat! We are on our all staff call until 12:30pm EDT. Perhaps, sometime this early afternoon? We are flexible and very grateful for Dr. Hahn's time.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:22 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Adding the right email for Katie this time!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 11:20 AM  
**To:** Caitlin\_Affolter@daines.senate.gov; katie\_schoettler@damines.senate.gov  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Ladies—do you have a few minutes to chat about this event this morning? I'm at (b)(6) if so. I'm trying to track down a few pieces of info, but I think it's likely Dr. Hahn will be able to participate once I can confirm a few things. Thank you

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:36 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:19 AM  
**To:** 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event. Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**  
*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: 301-796-6833 / Main office 301-796-5000  
Christina.Goldie@fda.hhs.gov



---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Friday, July 10, 2020 11:00 AM  
**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Sent:** Wednesday, July 8, 2020 1:09 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,

Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines; (b)(6)  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines; (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

**Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Goldie, Christina [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4511E64A9FCD44DB933F961260DE0F42-CHRISTINA.G]  
**Sent:** 7/15/2020 3:58:47 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Okay, thanks.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, July 15, 2020 3:47 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Make sure Maren knows and prepares him appropriately. Thanks.

Sent from my iPhone

On Jul 15, 2020, at 2:41 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

Hey Keagan,

Just looping you in. I saw the Q&A was not planned and wanted to make sure you knew that. Ok?

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Wednesday, July 15, 2020 2:10 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi—we got some TPs from Stephanie and Wolf and will use those so I think we are good on that front. We will also do a background/run of show memo to walk him through if that works for everyone?

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Sent:** Wednesday, July 15, 2020 1:00 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Thanks for sending this forward. Looks like we need some prepared remarks for about 5 minutes with 20 minutes Q&A from the group. Do we have a sense of the questions at all? I have cc'd Alex Wohl to coordinate the remarks for Dr. Hahn unless your office had plans to coordinate the remarks. Please let me know. Thanks.

**Christina M. Goldie (Chrisy)**  
*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration



Tel: 301-796-6833 / Main office 301-796-5000  
Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 12:49 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Attached is the form. I think we may need to update the date though since the event is now next Wednesday at 2:30.

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 5:56 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Thanks, Maren. Attached is the completed event request form. Let me know if you have any questions or need additional information from me.

Rachel

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 4:28 PM

**To:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Rachel—thanks for chatting! We will get back to you on the participants, as well as some other date/times options as soon as I can connect with the Commissioner's scheduler.

Can you help us fill out the attached form?

Many thanks!

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 3:58 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Maren—below is a list of folks we intend to invite to the virtual roundtable. Please let us know if there is an issue with including Jay Evans, Director for the Center of Translational Medicine at UM.

- Scott Ellner – CEO of Billings Clinic
- Craig Lambrecht – CEO of Kalispell Regional Healthcare
- John Hill – President & CEO of Bozeman Health
- John Goodnow – CEO of Benefis Health System (Great Falls)
- Dr. Dean French – CEO of Community Medical Center (Missoula)
- Cherie Taylor – CEO of Northern Rockies Medical Center (Cut Bank)
- Laura Merchant – CEO of Liberty Medical Center (Chester)
- Maria Clemons – CEO of Northwest Montana Community Health Center (Libby, Troy)
- William Keifer – CEO of Marias Medical Center, (b)(6) Toole County
- Jay Evans – Director for Center for Translational Medicine (UM)

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 2:42 PM

**To:** Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey can we chat quickly? Have a scheduling issue on our end. I'm at (b)(6)

---

**From:** Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 2:30 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Please find below the zoom information. Will you all have anyone else joining in addition to Dr. Hahn? We will send our attendees shortly. As mentioned, press will be on the zoom but on mute only.

caitlin\_affolter@daines.senate.gov is inviting you to a scheduled ZoomGov meeting.

Topic: Senator Daines, FDA Commissioner Hahn Virtual Roundtable on COVID-19 Vaccine, Update  
Time: Jul 16, 2020 04:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting  
https://senate.zoomgov.com/ (b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

(b)(6) JS (San Jose)  
JS (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

+1 646 828 7666 US (New York)

Meeting ID: (b)(6)

Password: (b)(6)

Find your local number: (b)(6)

Join by SIP

16161427115@sip.zoomgov.com

Join by H.323

(b)(6) US West)  
US East)

Meeting ID: (b)(6)

Password: (b)(6)

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 4:06 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Guys—

Thanks so much for talking earlier. Commissioner Hahn is looking forward to discussing FDA's work related to COVID-19 vaccines with the Senator and other folks later this week at the Roundtable.

Given that this is an official event, the political activity restrictions in federal law including the Hatch Act will apply to the Commissioner's participation. As I mentioned on the phone, there are a few items listed below I was hoping I could get clarified on your end.

- Please confirm that this will be an official event for the Senator and not a campaign event.

- Please confirm that the Senator's costs associated with this event will be paid for with his official funds and not campaign funds and staffed only by official staff only (ie no campaign staff).
- Please confirm that there will be no discussion or remarks related to the upcoming elections during the event and the Senator will be using official resources, including his Member's Representational Allowance (or comparable official budget funds).
- Please confirm that any photos associated with the event may only be used for non-campaign related purposes.
- Also, when you guys know, can you please email us the names/titles of the other participants?
- And finally, I have also cc'ed our communications POCs—Stephanie Cacco and John Wagner—for you guys to connect.

Thanks much!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 12:42 PM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Invite coming shortly

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 12:04 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Confirmed for 1:30pm EDT. If you could send us a calendar invite that would be great. I have cc'd everyone from our crew that will be on the line.

Katie, Comms  
 Rachel, Health LA  
 Dan and Liz, MT state staff (who will discuss the invitees)  
 And me from scheduling 😊

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:56 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen,

Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Great. Does 1:30 work for you guys? Want to call me or should I send a call-in invite (if you both want to join)? Thanks!

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Monday, July 13, 2020 11:54 AM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

We are happy to chat! We are on our all staff call until 12:30pm EDT. Perhaps, sometime this early afternoon? We are flexible and very grateful for Dr. Hahn's time.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 11:22 AM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Adding the right email for Katie this time!

---

**From:** McBride, Maren

**Sent:** Monday, July 13, 2020 11:20 AM

**To:** Caitlin\_Affolter@daines.senate.gov; katie\_schoettler@damines.senate.gov

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Ladies—do you have few minutes to chat about this event this morning? I'm at (b)(6) if so. I'm trying to track down a few pieces of info, but I think it's likely Dr. Hahn will be able to participate once I can confirm a few things. Thank you

---

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

**Sent:** Friday, July 10, 2020 2:36 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 11:19 AM

**To:** 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event.

Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: 301-796-6833 / Main office 301-796-5000  
Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Sent:** Wednesday, July 8, 2020 1:09 PM

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

**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDA's Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

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

To: Hahn, Stephen <SH1@fda.hhs.gov>

Cc: Steve Daines (b)(6)

Sent: Wed, Jul 8, 2020 9:30 am

Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.



**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 7/16/2020 9:44:20 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background material for 10:00 a.m. Telecon: CTAP Operations / Process  
**Attachments:** 1000-1-CTAP Operations Meeting Agenda\_20200716.docx; 1000-2-CTAP Commisioner's briefing.pptx

Background material for 10:00 a.m. Telecon: CTAP Operations / Process

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**From:** Flowers, Susan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9418B62EC07642D7BC53C564E008F5CE-SUSAN.FLOWE]  
**Sent:** 7/16/2020 9:57:08 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Background material for 10:00 a.m. Telecon: CTAP Operations / Process  
**Attachments:** 1000-2-CTAP Commisioner's briefing (002).pptx; 1000-1-CTAP Operations Meeting Agenda\_20200716.docx

Updated Background Material for 10:00 a.m. Telecon: CTAP Operations / Process

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**Sent:** 7/16/2020 11:40:56 AM  
**To:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]  
**Subject:** RE: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine

Yes, and

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Thursday, July 16, 2020 11:35 AM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine  
**Importance:** High

Should this go to Anna and Mark Abdo?  
S

---

**From:** Robert Kadlec <Robert.Kadlec@hhs.gov>  
**Date:** Thursday, July 16, 2020 at 11:33 AM  
**To:** Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, "Zebley, Kyle (OS)" <Kyle.Zebley@hhs.gov>, "Houchens, Christopher (OS)" <Christopher.Houchens@hhs.gov>  
**Cc:** Stephen Hahn <(b)(5)@fda.hhs.gov>, Garrett Grigsby <Garrett.Grigsby@hhs.gov>  
**Subject:** FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine

(b)(5)

(b)(5)

Best Bob

---

**From:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>  
**Sent:** Thursday, July 16, 2020 10:43 AM  
**To:** Kadlec, Robert (OS/ASPR/IO) <Robert.Kadlec@hhs.gov>  
**Cc:** Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>  
**Subject:** FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine  
**Importance:** High

Boss—

(b)(5)

per discussion earlier today.

Chris

---

**From:** Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>  
**Sent:** Wednesday, July 15, 2020 3:59 PM  
**To:** Hassell, David (Chris) (OS/ASPR/IO) <David.Hassell@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>  
**Subject:** FW: Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine  
**Importance:** High

Dr. Hassell and Bryan,

(b)(5)

(b)(5)

Please advise.

Regards,  
Jack

Jack Herrmann, MEd, NCC, LMHC  
Director (Acting), National Healthcare Preparedness Programs  
Office of Emergency Management and Medical Operations, Readiness Division  
Office of the Assistant Secretary for Preparedness and Response

---

**HEALTH AND HUMAN SERVICES (DHHS)** | Thomas P. O'Neill Federal Building | 200 C Street SW | Washington, DC 20515  
o. (202) 205-5886 | n[REDACTED] (b)(6)  
jack.herrmann@hhs.gov | www.phe.gov

*Disclaimer:*

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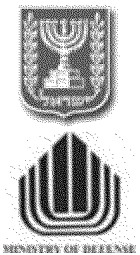
---

**From:** Mod-dep <Mod-dep@mod.gov.il>  
**Sent:** Wednesday, July 15, 2020 2:35 PM  
**To:** Herrmann, Jack (OS/ASPR/OEA) <John.Herrmann@hhs.gov>  
**Cc:** MOD-att <MOD-att@mod.gov.il>  
**Subject:** Letter from Mr. Edri to assistant secretary Kadlec - COVID-19 vaccine

Dear Jack,

Following our call – attached is the letter for Assistant Secretary Kadlec, please let me know that he got it.

Stay safe,



**Ori Katzav**  
Senior Advisor for Policy & Defense Cooperation

Ministry of Defense | Embassy of Israel in the US  
●office: 202-364-5608  
Email: mod-dep@mod.gov.il

#WLOu

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 7/17/2020 3:58:54 PM  
**To:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**CC:** Wohl, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ee6d17fe8114d16bc6244f59d9d00b4-Alexander.W]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Earley, Rosemary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05737f759eb54e9188cb16cbbe467d12-Rosemary.Ea]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Flahive, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=570655c122f24177ba6e9ac768a6f731-James.Flahi]; Wagner, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8a481c74326041d0b268d42f2d70d9f5-John.Wagner]; 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]  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Ok.

Sent from my iPhone

On Jul 17, 2020, at 3:57 PM, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov> wrote:

Hi, I think it still needs to be at the hhs studio though because it will a Zoom event.

---

**From:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Sent:** Friday, July 17, 2020 3:53 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

I definitely agree. Keagan, if you're ok with that, I will finalize the talking points and put into his homework with a few other items.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Friday, July 17, 2020 3:52 PM

**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Cc:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

I think a conversation is more of what they are looking for so if others are ok w no teleprompter I think that is the way to go.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 17, 2020 at 3:43:42 PM EDT  
**To:** Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Cc:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>, McBride, Maren <Maren.McBride@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>, Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>, Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Flahive, James <James.Flahive@fda.hhs.gov>, Wagner, John <John.Wolf.Wagner@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

I would think this should be less formal. Maren, any sense from Senators office?

Sent from my iPhone

On Jul 17, 2020, at 3:42 PM, Wohl, Alexander <Alexander.Wohl@fda.hhs.gov> wrote:

(b)(5)

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 17, 2020 3:40 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

If this is just a zoom call, why do we need to be in the studio?

Sent from my iPhone

On Jul 17, 2020, at 3:25 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

Good afternoon all,

(b)(5)

I hope you all have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 4:17 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi—happy to follow whatever process is best for the remarks, as well as process for a live/virtual event. Rosie and myself are lead for the materials/event for OCA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 2:44 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen,



Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(5)

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 2:10 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi—we got some TPs from Stephanie and Wolf and will use those so I think we are good on that front. We will also do a background/run of show memo to walk him through if that works for everyone?

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 1:00 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Thanks for sending this forward. Looks like we need some prepared remarks for about 5 minutes with 20 minutes Q&A from the group. Do we have a sense of the questions at all? I have cc'd Alex Wohl to coordinate the remarks for Dr. Hahn unless your office had plans to coordinate the remarks. Please let me know. Thanks.

**Christina M. Goldie (Chris)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 12:49 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Attached is the form. I think we may need to update the date though since the event is now next Wednesday at 2:30.

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 5:56 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Thanks, Maren. Attached is the completed event request form. Let me know if you have any questions or need additional information from me.

Rachel

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 4:28 PM

**To:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Rachel—thanks for chatting! We will get back to you on the participants, as well as some other date/times options as soon as I can connect with the Commissioner's scheduler.

Can you help us fill out the attached form?

Many thanks!

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 3:58 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Maren—below is a list of folks we intend to invite to the virtual roundtable. Please let us know if there is an issue with including Jay Evans, Director for the Center of Translational Medicine at UM.

1. Scott Ellner – CEO of Billings Clinic
2. Craig Lambrecht – CEO of Kalispell Regional Healthcare
3. John Hill – President & CEO of Bozeman Health
1. John Goodnow – CEO of Benefis Health System (Great Falls)
2. Dr. Dean French – CEO of Community Medical Center (Missoula)
3. Cherie Taylor – CEO of Northern Rockies Medical Center (Cut Bank)
4. Laura Merchant – CEO of Liberty Medical Center (Chester)
5. Maria Clemons – CEO of Northwest Montana Community Health Center (Libby, Troy)
6. William Keifer – CEO of Marias Medical Center (b)(6) Toole County)
7. Jay Evans – Director for Center for Translational Medicine (UM)

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Tuesday, July 14, 2020 2:42 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey can we chat quickly? Have a scheduling issue on our end. I'm at (b)(6)

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Tuesday, July 14, 2020 2:30 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Please find below the zoom information. Will you all have anyone else joining in addition to Dr. Hahn? We will send our attendees shortly. As mentioned, press will be on the zoom but on mute only.

caitlin\_affolter@daines.senate.gov is inviting you to a scheduled ZoomGov meeting.

Topic: Senator Daines, FDA Commissioner Hahn Virtual Roundtable on COVID-19 Vaccine, Update

Time: Jul 16, 2020 04:00 PM Eastern Time (US and Canada)

Join ZoomGov Meeting

<https://senate.zoomgov.com>

(b)(6)

Meeting ID: (b)(6)

Password: (b)(6)

One tap mobile

(b)(6)

US (San Jose)

(b)(6)

US (New York)

Dial by your location

+1 669 254 5252 US (San Jose)

+1 646 828 7666 US (New York)

Meeting ID: (b)(6)

Password: (b)(6)

Find your local number: <https://senate.zoomgov.com/j/abAVZEUISB>

Join by SIP

(b)(6)

Join by H.323

(b)(6)

(US West)

(US East)

Meeting ID: (b)(6)

Password: (b)(6)

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 4:06 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Guys—

Thanks so much for talking earlier. Commissioner Hahn is looking forward to discussing FDA's work related to COVID-19 vaccines with the Senator and other folks later this week at the Roundtable.

Given that this is an official event, the political activity restrictions in federal law including the Hatch Act will apply to the Commissioner's participation. As I mentioned on the phone, there are a few items listed below I was hoping I could get clarified on your end.

1. Please confirm that this will be an official event for the Senator and not a campaign event.
2. Please confirm that the Senator's costs associated with this event will be paid for with his official funds and not campaign funds and staffed only by official staff only (ie no campaign staff).
3. Please confirm that there will be no discussion or remarks related to the upcoming elections during the event and the Senator will be using official resources, including his Member's Representational Allowance (or comparable official budget funds).
4. Please confirm that any photos associated with the event may only be used for non-campaign related purposes.
5. Also, when you guys know, can you please email us the names/titles of the other participants?

6. And finally, I have also cc'ed our communications POCs—Stephanie Cacco and John Wagner—for you guys to connect.

Thanks much!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 12:42 PM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Invite coming shortly

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 12:04 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Confirmed for 1:30pm EDT. If you could send us a calendar invite that would be great. I have cc'd everyone from our crew that will be on the line.

Katie, Comms  
Rachel, Health LA  
Dan and Liz, MT state staff (who will discuss the invitees)  
And me from scheduling 😊

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:56 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Great. Does 1:30 work for you guys? Want to call me or should I send a call-in invite (if you both want to join)? Thanks!

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 11:54 AM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

We are happy to chat! We are on our all staff call until 12:30pm EDT. Perhaps, sometime this early afternoon? We are flexible and very grateful for Dr. Hahn's time.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:22 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Adding the right email for Katie this time!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 11:20 AM  
**To:** Caitlin\_Affolter@daines.senate.gov; katie\_schoettler@damines.senate.gov  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Ladies—do you have few minutes to chat about this event this morning? I'm at (b)(6) so. I'm trying to track down a few pieces of info, but I think it's likely Dr. Hahn will be able to participate once I can confirm a few things. Thank you

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:36 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:19 AM  
**To:** 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event. Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice

<Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina

<Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,

Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Sent:** Wednesday, July 8, 2020 1:09 PM

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

**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines)

<Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel

(Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren

<Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas

<Karas.Gross@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDAs Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines; (b)(6)  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines; (b)(6)  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines



## **Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, [Caitlin\\_Affolter@daines.senate.gov](mailto:Caitlin_Affolter@daines.senate.gov), 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]  
**Sent:** 7/17/2020 4:06:46 PM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Goldie, Christina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4511e64a9fcd44db933f961260de0f42-Christina.G]  
**CC:** Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(5)

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**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Date:** July 17, 2020 at 3:42:39 PM EDT  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

+ Colin - any sense of his preference Colin?

Sent from my iPhone

On Jul 17, 2020, at 3:40 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

I was having go to the studio cause he will be at HHS. Will he want to do it from his office in HHS?

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Friday, July 17, 2020 3:40 PM  
**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>  
**Cc:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>  
**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

If this is just a zoom call, why do we need to be in the studio?

Sent from my iPhone

On Jul 17, 2020, at 3:25 PM, Goldie, Christina <Christina.Goldie@fda.hhs.gov> wrote:

Good afternoon all,

(b)(5)

I hope you all have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner  
U.S. Food and Drug Administration  
Tel: 301-796-6833 / Main office 301-796-5000  
Christina.Goldie@fda.hhs.gov

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<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 4:17 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi—happy to follow whatever process is best for the remarks, as well as process for a live/virtual event. Rosie and myself are lead for the materials/event for OCA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 2:44 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

(b)(5)

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 2:10 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi—we got some TPs from Stephanie and Wolf and will use those so I think we are good on that front. We will also do a background/run of show memo to walk him through if that works for everyone?

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 1:00 PM

**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

Thanks for sending this forward. Looks like we need some prepared remarks for about 5 minutes with 20 minutes Q&A from the group. Do we have a sense of the questions at all? I have cc'd Alex Wohl to coordinate the remarks for Dr. Hahn unless your office had plans to coordinate the remarks. Please let me know. Thanks.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

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<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Wednesday, July 15, 2020 12:49 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Cc:** Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Attached is the form. I think we may need to update the date though since the event is now next Wednesday at 2:30.

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>  
**Sent:** Tuesday, July 14, 2020 5:56 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Thanks, Maren. Attached is the completed event request form. Let me know if you have any questions or need additional information from me.

Rachel

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Tuesday, July 14, 2020 4:28 PM  
**To:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Rachel—thanks for chatting! We will get back to you on the participants, as well as some other date/times options as soon as I can connect with the Commissioner's scheduler.

Can you help us fill out the attached form?

Many thanks!

---

**From:** Green, Rachel (Daines) <Rachel.Green@daines.senate.gov>  
**Sent:** Tuesday, July 14, 2020 3:58 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Affolter, Caitlin (Daines) <Caitlin.Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie.Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan.Stusek@daines.senate.gov>; Dellwo, Liz (Daines) <Liz.Dellwo@daines.senate.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Maren—below is a list of folks we intend to invite to the virtual roundtable. Please let us know if there is an issue with including Jay Evans, Director for the Center of Translational Medicine at UM.

- Scott Ellner – CEO of Billings Clinic
- Craig Lambrecht – CEO of Kalispell Regional Healthcare
- John Hill – President & CEO of Bozeman Health
- John Goodnow – CEO of Benefis Health System (Great Falls)



Find your local number: <https://senate.zoomgov.com/j/abAVZEUISB>.

Join by SIP

(b)(6)

Join by H.323

(b)(6)

US West)  
US East)

Meeting ID:

Password:

(b)(6)

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**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>

**Sent:** Monday, July 13, 2020 4:06 PM

**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines)

<Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Wagner, John <John.Wolf.Wagner@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hey Guys—

Thanks so much for talking earlier. Commissioner Hahn is looking forward to discussing FDA's work related to COVID-19 vaccines with the Senator and other folks later this week at the Roundtable.

Given that this is an official event, the political activity restrictions in federal law including the Hatch Act will apply to the Commissioner's participation. As I mentioned on the phone, there are a few items listed below I was hoping I could get clarified on your end.

- Please confirm that this will be an official event for the Senator and not a campaign event.
- Please confirm that the Senator's costs associated with this event will be paid for with his official funds and not campaign funds and staffed only by official staff only (ie no campaign staff).
- Please confirm that there will be no discussion or remarks related to the upcoming elections during the event and the Senator will be using official resources, including his Member's Representational Allowance (or comparable official budget funds).
- Please confirm that any photos associated with the event may only be used for non-campaign related purposes.
  
- Also, when you guys know, can you please email us the names/titles of the other participants?
- And finally, I have also cc'ed our communications POCs—Stephanie Caccomo and John Wagner—for you guys to connect.

Thanks much!

---

**From:** McBride, Maren  
**Sent:** Monday, July 13, 2020 12:42 PM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Invite coming shortly

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 12:04 PM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Stusek, Dan (Daines) <Dan\_Stusek@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Dellwo, Liz (Daines) <Liz\_Dellwo@daines.senate.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Confirmed for 1:30pm EDT. If you could send us a calendar invite that would be great. I have cc'd everyone from our crew that will be on the line.

Katie, Comms  
Rachel, Health LA  
Dan and Liz, MT state staff (who will discuss the invitees)  
And me from scheduling 😊

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:56 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Great. Does 1:30 work for you guys? Want to call me or should I send a call-in invite (if you both want to join)? Thanks!

---

**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>  
**Sent:** Monday, July 13, 2020 11:54 AM  
**To:** McBride, Maren <Maren.McBride@fda.hhs.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>  
**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Maren,

We are happy to chat! We are on our all staff call until 12:30pm EDT. Perhaps, sometime this early afternoon? We are flexible and very grateful for Dr. Hahn's time.

---

**From:** McBride, Maren <Maren.McBride@fda.hhs.gov>  
**Sent:** Monday, July 13, 2020 11:22 AM  
**To:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines)



<Katie\_Schoettler@daines.senate.gov>

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Adding the right email for Katie this time!

---

**From:** McBride, Maren

**Sent:** Monday, July 13, 2020 11:20 AM

**To:** Caitlin Affolter@daines.senate.gov; katie\_schoettler@damines.senate.gov

**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>

**Subject:** FW: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi Ladies—do you have few minutes to chat about this event this morning? I'm at (b)(6) if so. I'm trying to track down a few pieces of info, but I think it's likely Dr. Hahn will be able to participate once I can confirm a few things. Thank you

---

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

**Sent:** Friday, July 10, 2020 2:36 PM

**To:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>; 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Sorry for the confusion here folks. Getting some conflicting reports from our General Counsels office on the Commissioner's participation. Hopefully we get an answer back quickly to let you know who will be attending for the FDA.

---

**From:** Goldie, Christina <Christina.Goldie@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 11:19 AM

**To:** 'Affolter, Caitlin (Daines)' <Caitlin\_Affolter@daines.senate.gov>; Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hoffman, Allison <Allison.Hoffman@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Good morning Caitlin,

You can contact Allison Hoffman in Dr. Abernethy's office to coordinate this event.

Allison.hoffman@fda.hhs.gov I have also cc'd her on this email. Please let me know if we can assist any further. Thank you and have a great weekend.

**Christina M. Goldie (Chrisy)**

*Lead Management Analyst / Notary*

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Tel: 301-796-6833 / Main office 301-796-5000

Christina.Goldie@fda.hhs.gov

<image001.png>

<image002.jpg>

<image003.jpg>

<image004.jpg>

<image005.jpg>

<image006.jpg>

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**From:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>

**Sent:** Friday, July 10, 2020 11:00 AM

**To:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>

**Cc:** Thacker, Darin (Daines) <Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines)

<Jason\_Thielman@daines.senate.gov>; Green, Rachel (Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice

<Janice.Sheehy@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Goldie, Christina

<Christina.Goldie@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>

**Subject:** RE: Hi Keagan, Virtual Roundtable event with Senator Daines

Hi All,

We understand the virtual will be with Dr. Amy Abernethy instead of Dr. Hahn. Would 4pm EDT on Thursday, July 16<sup>th</sup> work for Dr. Abernethy?

Warm Regards,  
Caitlin

---

**From:** Schoettler, Katie (Daines) <Katie\_Schoettler@daines.senate.gov>

**Sent:** Wednesday, July 8, 2020 1:09 PM

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

**Cc:** Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov>; Thacker, Darin (Daines)

<Darin\_Thacker@daines.senate.gov>; Thielman, Jason (Daines) <Jason\_Thielman@daines.senate.gov>; Green, Rachel

(Daines) <Rachel\_Green@daines.senate.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; McBride, Maren

<Maren.McBride@fda.hhs.gov>; Goldie, Christina <Christina.Goldie@fda.hhs.gov>; Gross, Karas

<Karas.Gross@fda.hhs.gov>

**Subject:** Re: Hi Keagan, Virtual Roundtable event with Senator Daines

Yes, that should be fine. Thx

Sent from my iPhone

On Jul 8, 2020, at 12:19 PM, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov> wrote:

Thanks, Caitlin.

We are running the traps to see if he can participate and will get back to you shortly. One thing though, can we change Operation Warp Speed and say something like FDAs Role in Vaccine and Therapeutics for COVID-19? We are trying to keep the Commissioner clear of the OWS work. I am also including our leg team and scheduling team to find the time if cleared.

Thanks,  
Keagan

Sent from my iPhone

On Jul 8, 2020, at 12:11 PM, Affolter, Caitlin (Daines) <Caitlin\_Affolter@daines.senate.gov> wrote:

Hi Keagan,

We greatly appreciate Dr. Hahn's willingness to join Senator Daines on a virtual roundtable. Is next Thursday, July 16<sup>th</sup> at 4pm EDT available? It would be the zoom platform for 30 minutes. We can certainly be flexible that afternoon and happy to send additional dates too. I have cc'd our Daines team that can follow up with further information.

We look forward to hearing from you.

Warm Regards,  
Caitlin

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
To: Hahn, Stephen <SH1@fda.hhs.gov>  
Cc: Steve Daines <(b)(6)>  
Sent: Wed, Jul 8, 2020 9:30 am  
Subject: Re: Virtual Roundtable event with Senator Daines

Will do, Commissioner.

Sent from my iPhone

On Jul 8, 2020, at 11:29 AM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

Thank you for the invitation Senator. Sounds like an important event. I am copying my Chief of Staff, Keagan Lenihan, who can get this request through the system.

Best  
Steve

---

**From:** Steve Daines <(b)(6)>  
**Date:** July 8, 2020 at 9:06:05 AM MDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Subject:** Virtual Roundtable event with Senator Daines

**Senator Daines, FDA Commissioner Hahn, and Montana Hospital Leaders Virtual Roundtable**

**Title and Location of the Event:** Roundtable Discussion (Zoom) with FDA Commissioner Stephen Hahn on Operation Warp Speed – Virtual

**Date of the Event:** Week of July 13th -- 30 minutes

**Points of Contact:** Caitlin Affolter, Caitlin Affolter@daines.senate.gov, 202-774-8222

**Description and Objective:** This will be a virtual roundtable with Dr. Hahn, Senator Daines, and hospital CEOs and local officials in Montana designed to give the Administration the ability to highlight the important work being done through Operation Warp Speed (OWS) to develop and manufacture COVID-19 vaccines and therapeutics.

**Background on Senator Daines' Work:** OWS is being funded through the CARES Act as a result of Senator Daines' leadership to secure \$10 billion to help accelerate the development and manufacturing of COVID-19 vaccines and therapeutics.

**Specific Requests:** Commissioner Hahn would participate in the roundtable by providing opening remarks, an overview of the goals of Operation Warp Speed and recent developments, and take questions from roundtable participants.

**Expected Attendees:** 5-8 individuals

**Additional Speakers:** Senator Daines, hospital leaders, and selected local officials

**Open or closed to press?** Open to local and targeted national press. Daines communications teams will control questions asked from specific reporters.

---

**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/17/2020 10:32:03 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniel]  
**Subject:** 130\_CovidVitals\_17 July 2020.docx  
**Attachments:** 130\_CovidVitals\_17 July 2020.docx; ATT00001.txt

vitals today

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
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**Attachments:** Vaccine Site Visits\_Remarks\_DRAFT\_SC\_7.26.20.docx; ATT00001.txt

**From:** Chukwudebe, Nnaemeka [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=510E95FD635344B89E21E3D249D57046-NNAEMEKA.CH]  
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Helmanis, Lisa M [/o=ExchangeLabs/ou=Exchange Administrative Group

CC:



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(FYDIBOHF23SPDLT)/cn=Recipients/cn=4345183932aa42a99c9adb79dfc1ba4b-LHELMANI]

**Subject:** REMINDER UPDATE: Due 2 pm Tuesday, July 28, 2020; HHS Week Ahead Report Input

**Attachments:** DRAFT Week Ahead Report.docx; WAR Final 7-22-20.docx

**PLEASE NOTE THAT THE WAR HAS NOW CHANGED BACK TO WEEKLY UPDATE STATUS.**

Dear Contacts:

Attached is the draft/template of the **HHS Week Ahead Report** for Thursday **7/30/2020** and the most recent final report (sent on 7/22/2020).

- Please resubmit items from the previous week's reports that are pending approval by the Department and/or OMB and update the status or crucial due dates. These items will list under: **"Items Under HHS Review"** and **"Items Under OMB Review."**
- **"Items for Awareness"** that have been listed in previous weeks do not require relisting.
- Please email your submissions to **Emeka Chukwudebe** and **Lisa Helmanis** by **2:00 pm Tuesday, July 28.**

***The Department needs this finalized report on Wednesday, so prompt submissions are crucial.***

*Note: The Department has requested that we embed newly submitted documents for reference. (Please check that embedded documents are not locked.)*

*And please PDF documents (if necessary) to reduce file size when embedding to enable transmitting to the Department.*

As a reminder, below are the information sources RPMS will be using for the report:

- *Federal Register* documents: OP/RPMS (Ken Cohen, Tarita Rooths)
- Correspondence: OES (Martina Varnado/Jeff O'Neill)
- Congressional hearings, meetings, and correspondence: OL—Associate Commissioner for Legislation (Karas Gross)
- Congressional activities related to appropriations issues or members, including: hearings, meetings, requests and correspondence: OCA—Legislative Director for Appropriations (Maren McBride)
- Policy-related public meetings and presentations, speaking engagements, responses to citizen petitions, and other actions: Center/Office Leadership—Working through Exec Sec Contacts

Please work with your Center/Office leadership to compile your weekly submission for this Report. And please continue working with your contacts in the Commissioner's Office, including those in the Office of Policy and Office of Legislation, to strategically plan your submissions.

Sincerely,

**Emeka Chukwudebe**  
**Regulations Policy and Management Staff (RPMS)**  
**Office of Policy**  
**U.S. Food and Drug Administration**  
Tel: (240) 472-2915  
nnaemeka.chukwudebe@fda.hhs.gov



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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/27/2020 7:25:17 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniell]  
**Subject:** 136\_CovidVitals\_27 July 2020.docx  
**Attachments:** 136\_CovidVitals\_27 July 2020.docx; ATT00001.txt

FDA Vitals

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**From:** Sheehy, Janice [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F45A6C96F5274724A1BE5970EB648FF7-JSHEEHY]  
**Sent:** 7/28/2020 7:49:36 AM  
**To:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**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]  
**Subject:** FW: HHS JIC Daily Communications Summary - July 27, 2020  
**Attachments:** 7.27.2020 HHS JIC COVID-19 Daily Communications Report.pdf

Hi Keagan, does this document need to be (b)(5) Thanks! -j

---

**From:** Hahn, Stephen <SH1@fda.hhs.gov>  
**Sent:** Monday, July 27, 2020 5:08 PM  
**To:** Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: HHS JIC Daily Communications Summary - July 27, 2020

For kitchen cabinet.  
Thanks  
Steve

---

**From:** "Danko, Carol (OS/ASPR/IO)" <Carol.Danko@hhs.gov>  
**Date:** Monday, July 27, 2020 at 4:04 PM  
**To:** "Danko, Carol (OS)" <Carol.Danko@hhs.gov>  
**Cc:** "Jic, Covid (OS)" <JIC@hhs.gov>  
**Subject:** HHS JIC Daily Communications Summary - July 27, 2020

Dear Senior Leaders,  
Please find attached today's Daily Communications Summary. Moving forward, please expect this by noon.  
Thanks,  
Carol Danko

(b)(6)

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**From:** Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]  
**Sent:** 7/31/2020 9:37:06 PM  
**To:** Alex Azar II [AMA2@hhs.gov]  
**CC:** Harrison, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ac2bfe7febef45ed98c87b83e5bcf8d0-HHS-Brian.H]; Abel, Daniel B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63894853fa3a403fa69b1019217fac74-HHS-Daniel.]; Steele, Danielle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=634b96dc13cf48f3971ce676b65e952f-HHS-Daniel]  
**Subject:** 140\_CovidVitals\_31 July 2020.docx  
**Attachments:** 140\_CovidVitals\_31 July 2020.docx; ATT00001.txt

Vitals for today.

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 2/28/2020 3:31:38 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Friday, February 28, 2020

## TODAY

### FDA Briefings for Congress

- Senate HELP Bipartisan staff briefing on drug donations/DSCSA
- Phone call with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- Phone call with Sen. Martha McSally (R-AZ) and Dr. Jeff Shuren
- House Bipartisan member briefing on COVID-19
- Bicameral Hill staff briefing on COVID-19
- Meeting with Reps. Diana DeGette (D-CO), Fred Upton (R-MI) and Commissioner Hahn

### Outreaches

- REVISED: Coronavirus (COVID-19) Supply Chain Update

### Correspondence

- Rep. Cathy McMorris Rodgers (R-WA) +17 urge the Agency to implement and fully enforce T21 policy to eliminate teen usage of vaping products

### Media

- Rep. Mo Brooks (R-AL): US #Capitol #coronavirus #COVID19 update by CDC FDA NIH

\*90% of all USA drug content comes from China

\*USA challenge is still low risk

\*NO USA quarantine helpers have COVID19

\*USA testing kits more available

\*USA has PERFECT zero fatality record

\*COVID19 NOT man-made

- Sen. Josh Hawley (R-MO): FDA announces first drug shortage due to #coronavirus. This underscores need to secure our medical supply chain now.
- Rep. David Kustoff (R-TN): This morning, I was briefed by the @CDCgov, @NIH, @US\_FDA, @HHSgov, and others on the #coronavirus. We are working to ensure West Tennesseans and people across our nation are prepared and fully informed. For more information, click the website below.
- Rep. Julia Brownley (D-CA): Today, I voted for the Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act, which:

⊗ Gives FDA authority to regulate all tobacco products, incl. e-cigarettes

⊗ Invests in smoking and vaping cessation programs

⊗ Prohibits marketing e-cigarettes to children

- Rep. Sylvia Garcia (D-TX): Nearly all tobacco use begins during youth and young adulthood. That's why Congress passed the Protecting American Lungs and Reversing the Youth Tobacco Epidemic Act, which will provide the FDA with the tools and resources needed to respond to this public health crisis.

- Rep. Andy Barr (R-KY):

- ✓ Passing T21 banning the sale of Tobacco and e-cigarettes to minors under 21
- ✓ Trump administration issued guidance banning JUUL-like e-vapor products
- ✓ FDA now has authority to pull any “kid friendly” e-vapor products off the market

- Rep. Kathy Castor (D-FL): @US\_FDA and @CDCgov report a 78% increase in e-cigarette use by high school students & 48% among middle school students from 2017-2018. #endvaping

- Rep. Eliot Engel (D-NY): Today the House passed H.R. 2339, legislation to turn the tide in the youth tobacco epidemic. This legislation includes provisions I authored to update the FDA’s anti-tobacco campaigns for young adults.

#### COMING UP

- 3/2 Phone call with Rep. John Moolenaar (R-MI) and Commissioner Hahn
- 3/3 Senate HELP Hearing on An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus; Commissioner Hahn will be testifying for the Agency.
- 3/3 Senate HELP Bipartisan staff briefing on clinical decision support
- 3/3 Meeting with Rep. Diana DeGette (D-CO) and Commissioner Hahn
- 3/4 Senate HELP Bipartisan staff briefing on Pediatric Rare Disease PRV
- 3/4 Senate Drug Caucus Minority briefing on clinical trial reporting
- 3/4 Phone call with Rep. Buddy Carter (R-GA) and Commissioner Hahn
- 3/5 Meeting with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- 3/5 House E&C Bipartisan staff briefing on MODERN Labeling
- 3/6 Senate HELP Minority staff briefing on orphan drugs
- 3/11 Senate HELP Minority staff briefing on YF-Vax Shortage

*The Office of Legislation (OL), an office within the Office of Policy, Legislation, and International Affairs (OPLIA), directs and manages FDA’s engagement with Congress. Please feel free to contact OL staff directly or via 301-796-8900 or [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov). For matters specific to the congressional budget and appropriations process, please contact the Office of Congressional Appropriations (OCA) at 240-402-2718 or [jenna.zembower@fda.hhs.gov](mailto:jenna.zembower@fda.hhs.gov).*

---

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/2/2020 3:30:17 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Monday, March 2, 2020

## TODAY

### FDA Briefings for Congress

- Bicameral Hill staff briefing on COVID-19

### Media

- Sen. Jeanne Shaheen (D-NH): Coronavirus is a serious threat—it is by no means a “hoax.” As a nation and a state, we need to be working together, preparing for the worst and hoping for the best. I encourage everyone to heed the precautions of public health officials and stay informed as this virus spreads.
- Rep. Bob Latta (R-OH): The first & most important job our government has is to keep Americans safe. As we continue to closely monitor the spread of the coronavirus, close collaboration between the @CDCgov, @US\_FDA & our state & local #publichealth partners will be vital in making significant progress.

### COMING UP

- 3/3 Senate HELP Hearing on An Emerging Disease Threat: How the U.S. Is Responding to COVID-19, the Novel Coronavirus; Commissioner Hahn will be testifying for the Agency.
- 3/3 Senate HELP Bipartisan staff briefing on clinical decision support
- 3/3 Meeting with Rep. Diana DeGette (D-CO) and Commissioner Hahn
- 3/4 Senate HELP Bipartisan staff briefing on Pediatric Rare Disease PRV
- 3/4 Senate Drug Caucus Minority briefing on clinical trial reporting
- 3/4 Phone call with Rep. Buddy Carter (R-GA) and Commissioner Hahn
- 3/5 Meeting with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- 3/5 House E&C Bipartisan staff briefing on MODERN Labeling
- 3/6 Senate HELP Minority staff briefing on orphan drugs
- 3/11 Senate HELP Minority staff briefing on YF-Vax Shortage

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/4/2020 4:01:17 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Wednesday, March 4, 2020

## TODAY

Rep. Brad Schneider (D-IL) introduced legislation to address shortages of medical devices.

Rep. Hakeem Jeffries (D-NY) introduced legislation to expand the tropical disease product priority review voucher program to encourage treatments for coronavirus.

## FDA Briefings for Congress

- Senate HELP Bipartisan staff briefing on Pediatric Rare Disease PRV
- Senate Drug Caucus Minority briefing on clinical trial reporting
- Phone call with Rep. Buddy Carter (R-GA) and Commissioner Hahn

## Outreaches

- FDA warns of potential medical device cybersecurity vulnerability
- FDA Takes Rare Step to Ban Electrical Stimulation Devices for Self-Injurious or Aggressive Behavior
- FDA releases final guidance related to the upcoming biological product transition
- New 'Feed Your Mind' Initiative Launches to Increase Consumer Understanding of Genetically Engineered Foods

## Media

- U.S. Surgeon General: Important #Coronavirus #covid19 updates: 1) @US\_FDA says 46 state public health labs in addition to @CDCgov now doing testing. I visited the CT @CTDPH lab yesterday and they are up and running. 2) ANY doctor can have their patient tested for Coronavirus. @AmerMedicalAssn @VP
- Sen. Lamar Alexander (R-TN): Today, I chaired a Senate health committee hearing to hear from @CDCgov, @PHEgov, @NIH and @US\_FDA, which reminded me of why most experts believe that the United States is better prepared than any country to deal with a health crisis like the #coronavirus.
- Rep. Mike Gallagher (R-WI): The coronavirus outbreak has revealed severe vulnerabilities in our medical supply chain. That's why @repmarkpocan and I introduced HR 6049 to ensure the FDA better identifies potential shortages and protects access to lifesaving medicines and supplies.
- Rep. Raja Krishnamoorthi (D-IL): Today, as an @OversightDems Subcommittee Chairman, I requested information from @HHSgov, @CDCgov, and @US\_FDA on their testing procedures for the #coronavirus following troubling reports that their test kits may be inaccurate.
- Sen. Lisa Murkowski (R-AK): Senate HELP Committee brought in reps from @CDCgov, @NIH, @HHSgov & @US\_FDA to delve into how the federal government is responding to the #Covid\_19 outbreak & actions the administration is taking to ensure that the U.S. is prepared for, and responding to, the emerging threat.
- Rep. Bill Pascrell (D-NJ): As the #coronavirus threat grows today I called on @FDA @FTC to crackdown on swindlers and snakeoil salesmen exploiting public fear by selling fraudulent medical treatments. This includes disgraced televangelist Jim Bakker who is hawking a fake coronavirus cure on his program.
- Rep. Brad Schneider (D-IL): The coronavirus outbreak is threatening the supply chain for medical devices we depend on to deliver life-saving care. Today, I introduced bipartisan legislation with @congressmanhice and @janschakowsky to help FDA fight shortages of medical equipment, such as respirator masks.



- Sen. Jeff Merkley (D-OR): BREAKING NEWS: An \$8.3 billion emergency aid package that exceeds the limited WH request has been agreed to. Votes later. It includes items I've pushed for to support CDC, FDA, local govts, & small biz. Communities in OR & across the country need help now.
- Sen. Kelly Loeffler (R-GA): As we continue monitoring the #coronavirus, I remain laser-focused on working to combat it in Georgia and the country. Under the leadership of @realDonaldTrump, @VP, @CDCgov, @NIH, @HHSgov, @US\_FDA and many more world-class experts, we will get this done.
- Rep. Carolyn Maloney (D-NY): The Trump Administration's response to the #CoronavirusOutbreak has been dysfunctional at best. Yesterday, I demanded info from @HHSgov, @CDCgov, & @US\_FDA about testing accuracy, diagnoses, and cost of treating #COVID19.

#### COMING UP

- 3/5 Senate Bipartisan member briefing on COVID-19; Dr. Anand Shah will represent the agency
- 3/5 Senate HELP Minority and House E&C Majority staff briefing on COVID-19
- 3/5 House member briefing on COVID-19; Dr. Anand Shah will represent the agency
- 3/5 House E&C Bipartisan staff briefing on MODERN Labeling
- 3/6 Bicameral Hill staff briefing on COVID-19
- 3/6 Senate HELP Minority and House E&C Majority staff briefing on COVID-19
- 3/6 Senate HELP Minority staff briefing on orphan drugs
- 3/6 House PSI Bipartisan staff briefing on ENDS
- 3/10 Meeting with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- 3/11 Senate HELP Minority staff briefing on YF-Vax Shortage
- 3/13 Senate HELP Minority staff briefing on clinical trial oversight
- 3/23 Senate HELP Bipartisan staff briefing on pharmacogenetics
- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn

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---

**Sent:** 3/5/2020 11:35:55 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: COVID-19 testing question

I don't mind calling, [REDACTED] (b)(5)

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 10:23 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Fwd: COVID-19 testing question

Would you be comfortable calling maribel and finding out what info she needs? If so I'll forward her number. I'm tied up til noon but will call if you are not comfortable doing so Thank you!

---

**From:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Date:** March 5, 2020 at 9:33:31 AM EST  
**To:** Ramos, Maribel <MRamos@nga.org>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: COVID-19 testing question

Hi Maribel. Looping in Karen Meister who is the acting IGA team director. She will be able to assist.

-- Nick

---

**From:** Ramos, Maribel <MRamos@nga.org>  
**Sent:** Thursday, March 5, 2020 9:27 AM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** COVID-19 testing question

Hello,

Are you available to get on a brief call this morning? We have an inquiry from a state regarding testing for coronavirus and the governor is very anxious to get answers. It may be easier to explain over the phone.

Thanks,  
Maribel

The information contained in this electronic transmission, including any attachments, is for the exclusive use of the intended recipient(s) and may contain information that is privileged, proprietary, and/or confidential. If the reader of this transmission is not an intended recipient, or a person responsible for delivering it to the intended recipient, you are hereby notified that any review, dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please immediately notify the sender and delete this message.

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**Sent:** 3/5/2020 12:47:24 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Are you available to talk now?

Did you want me to call you or are you at WO? I though

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 12:46 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Are you available to talk now?

Are you still at WO?

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Thursday, March 05, 2020 12:45 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Are you available to talk now?

Sure, but I have a 1pm meeting.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 12:42 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Are you available to talk now?

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Thursday, March 05, 2020 11:48 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: COVID-19 testing question

Sure.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 11:47 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: COVID-19 testing question

That's fine but let's talk this afternoon.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Thursday, March 05, 2020 11:41 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: COVID-19 testing question

Hi Karen,

Normally I would call, but because it's Coronavirus, I would prefer you calling. This is very high profile and I don't want to mess anything up.

Also, I had to come to campus for a meeting this morning, and was planning on staying on campus the rest of the day; if I (b)(6) Please let me know if that works for you.

Erica

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 5, 2020 10:23 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Fwd: COVID-19 testing question

Would you be comfortable calling maribel and finding out what info she needs? If so I'll forward her number. I'm tied up til noon but will call if you are not comfortable doing so Thank you!

---

**From:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Date:** March 5, 2020 at 9:33:31 AM EST  
**To:** Ramos, Maribel <MRamos@nga.org>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: COVID-19 testing question

Hi Maribel. Looping in Karen Meister who is the acting IGA team director. She will be able to assist.

-- Nick

---

**From:** Ramos, Maribel <MRamos@nga.org>  
**Sent:** Thursday, March 5, 2020 9:27 AM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** COVID-19 testing question

Hello,

Are you available to get on a brief call this morning? We have an inquiry from a state regarding testing for coronavirus and the governor is very anxious to get answers. It may be easier to explain over the phone.

Thanks,  
Maribel

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/5/2020 3:35:50 PM  
**To:** Mahoney, Elizabeth K (GOV) [elizabeth.k.mahoney@state.ma.us]; Ramos, Maribel [MRamos@nga.org]  
**CC:** McColaugh, Kevin (GOV) [kevin.mccolaugh@state.ma.us]; Sudders, Marylou (EHS) [marylou.sudders@state.ma.us]; Darcy, Leslie (EHS) [leslie.darcy@state.ma.us]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: Question from MA on COVID-19 Tests

Great. If you have questions after that, please let us know.

Karen

---

**From:** Mahoney, Elizabeth K (GOV) <elizabeth.k.mahoney@state.ma.us>  
**Sent:** Thursday, March 05, 2020 3:35 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Ramos, Maribel <MRamos@nga.org>  
**Cc:** McColaugh, Kevin (GOV) <kevin.mccolaugh@state.ma.us>; Sudders, Marylou (EHS) <marylou.sudders@state.ma.us>; Darcy, Leslie (EHS) <leslie.darcy@state.ma.us>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Question from MA on COVID-19 Tests

Correct, no need for a call today, we will plan to join the Town Hall tomorrow.

---

**From:** Meister, Karen G [mailto:Karen.Meister@fda.hhs.gov]  
**Sent:** Thursday, March 05, 2020 3:33 PM  
**To:** Mahoney, Elizabeth K. (GOV); Ramos, Maribel  
**Cc:** McColaugh, Kevin (GOV); Sudders, Marylou (EHS); Darcy, Leslie (EHS); White, Erica  
**Subject:** RE: Question from MA on COVID-19 Tests

So no need for phone call today?

---

**From:** Mahoney, Elizabeth K (GOV) <elizabeth.k.mahoney@state.ma.us>  
**Sent:** Thursday, March 05, 2020 3:32 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Ramos, Maribel <MRamos@nga.org>  
**Cc:** McColaugh, Kevin (GOV) <kevin.mccolaugh@state.ma.us>; Sudders, Marylou (EHS) <marylou.sudders@state.ma.us>; Darcy, Leslie (EHS) <leslie.darcy@state.ma.us>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Question from MA on COVID-19 Tests

Karen, thank you so much. This FDA Town Hall actually looks like a great opportunity for us to get more information about the process and should serve to answer the questions we have. Given that, and understanding how busy you must all be, we don't want to take up your time this afternoon. Really appreciate your willingness to get on the phone with us, though.

Thanks,  
Elizabeth

---

**From:** Meister, Karen G [mailto:Karen.Meister@fda.hhs.gov]  
**Sent:** Thursday, March 05, 2020 3:22 PM  
**To:** Mahoney, Elizabeth K. (GOV); Ramos, Maribel  
**Cc:** McColaugh, Kevin (GOV); Sudders, Marylou (EHS); Darcy, Leslie (EHS); White, Erica  
**Subject:** RE: Question from MA on COVID-19 Tests

FDA folks are available until 5 today. What time works for you all and I will send out a call in number?

Also, attached is an invitation to an FDA Town Hall on this subject which you may be interested in attending (by phone).

Looking forward to talking with you soon.

Karen

*Karen Meister, J.D.  
Acting Director, FDA Office of Intergovernmental Relations  
Senior Advisor, FDA Office of Legislation  
(301) 796-8916 office*

**(b)(6)** *(work cell)  
(personal cell- I will call you back on work phone)*

---

**From:** Mahoney, Elizabeth K (GOV) <elizabeth.k.mahoney@state.ma.us>  
**Sent:** Thursday, March 05, 2020 1:33 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Ramos, Maribel <MRamos@nga.org>  
**Cc:** McColaugh, Kevin (GOV) <kevin.mccolaugh@state.ma.us>; Sudders, Marylou (EHS) <marylou.sudders@state.ma.us>; Darcy, Leslie (EHS) <leslie.darcy@state.ma.us>  
**Subject:** RE: Question from MA on COVID-19 Tests

Thanks, Maribel and Karen. I am copying our Health and Human Services Secretary Marylou Sudders. Karen, we look forward to hearing from you about possible times for a call with the FDA.

Best,  
Elizabeth

---

**From:** Meister, Karen G [mailto:Karen.Meister@fda.hhs.gov]  
**Sent:** Thursday, March 05, 2020 11:29 AM  
**To:** Ramos, Maribel; Mahoney, Elizabeth K. (GOV)  
**Cc:** McColaugh, Kevin (GOV)  
**Subject:** RE: Question from MA on COVID-19 Tests

Thanks Maribel. Will be in touch soon.

---

**From:** Ramos, Maribel <MRamos@nga.org>  
**Sent:** Thursday, March 05, 2020 11:23 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Mahoney, Elizabeth K (GOV) <elizabeth.k.mahoney@state.ma.us>  
**Cc:** McColaugh, Kevin (GOV) <kevin.mccolaugh@state.ma.us>  
**Subject:** Question from MA on COVID-19 Tests

Hi Karen,

I have included Elizabeth Mahoney, Governor Baker's Deputy Chief of Staff and Policy Director, along with Kevin McColaugh, Governor Baker's Washington, DC Director, on this email.

As I mentioned over the phone, Governor Baker is looking to get answers on states developing their own testing for COVID-19. They have seen the guidance that was released by FDA but had questions in follow-up to what has been provided. Such as: What is the approval process? Who needs to approve? What is the timeline for approval? What criteria is FDA looking for in tests that are developed?

You had kindly offered to have a call and hear from them directly. Therefore, wanted to get everyone on the same page. Please provide times of availability. If possible, would love to be on – I know there will be additional questions from other states on this same issue.

Thank you,

Maribel

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/5/2020 3:43:56 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Thursday, March 5, 2020

## TODAY

Rep. Scott Peters (D-CA) introduced legislation to amend the Federal Food, Drug, and Cosmetic Act to reduce drug shortages.

## FDA Briefings for Congress

- Senate Bipartisan member briefing on COVID-19; Dr. Anand Shah represented the agency
- Senate HELP Minority and House E&C Majority staff briefing on COVID-19
- House member briefing on COVID-19; Dr. Anand Shah represented the agency
- House E&C Bipartisan staff briefing on MODERN Labeling

## Outreaches

- Notice to Compounders: Changes that affect compounding as of March 23, 2020
- FDA Releases Action Plan to Advance the Safety of Leafy Greens
- FDA Encourages Inclusion of Older Adult Patients in Cancer Clinical Trials, Draft Guidance

## Media

- Rep. French Hill (R-AR): The safety of the American people come first. Today, my colleagues and I passed an emergency funding package which provides \$7.8 billion to protect Arkansans from #COVID19. I applaud @NIH, @CDCgov, and @US\_FDA for already taking steps to limit the spread of #Coronavirus.
- Rep. Bob Latta (R-OH): I'm relieved House Democrats agreed to put politics aside in order to provide the @CDCgov, @US\_FDA, @StateDept, @USAID & our state & local response efforts the additional tools & supplies they need in order to safely respond to & better prepare for the spread of #COVID19.
- Sen. Roger Wicker (R-MS): The government needs to put patients first during the drug approval process. Today @SenAmyKlobuchar and I reintroduced the #BENEFITact to provide patients and advocates a larger role in the @US\_FDA's framework for drug approval.
- Rep. Jeff Fortenberry (R-NE): The House just passed a #coronavirus emergency bill. I voted for it. Half the funding goes to testing, treatments and vaccine development. Other money goes to state and local preparation and response and to ensure our drug supply is safe and available @US\_FDA
- Sen. Mitt Romney (R-UT): It's been 20 days since we raised this exact concern to @FDATobacco Director Zeller. Flavored e-cigarettes are still on the market, addicting our kids to nicotine. The @US\_FDA must put the health of our children ahead of tobacco companies' profits and eliminate vaping flavors.
- Sen. Pat Toomey (R-PA): Expanding our capacity to test for the coronavirus on a large scale is my priority right now. I have been in contact with the FDA, CMS, and the CDC in order to ensure that Pennsylvania's hospitals are able to administer all the coronavirus tests that Pennsylvanians need.
- Rep. Mike Doyle (D-PA): Electric shock therapy is cruel torture that should never be used on Americans with disabilities. I support the FDA's long-overdue decision to ban this practice at the Judge Rotenberg Center – it will help many patients who are still suffering.
- Rep. Salud Carbajal (D-CA): Just this morning, I attended another congressional briefing on the Coronavirus with @cdcgov, @StateDept, @NIH, @USAID, @HHSgov, @DHSgov, @DeptofDefense, @US\_FDA and health experts. We are confident this robust package will move on to the Senate and then the White House.



- Rep. Diana DeGette (D-CO): The #VALIDAct will overhaul the federal government's outdated system that is slowing down that process, while also increasing the reliability of such tests going forward.
- Sen. Richard Burr (R-NC): Our legislation will modernize the approval process at the FDA to allow diagnostic test developers to keep pace with today's medical advancements, create tests that discover disease more quickly, and ensure Americans can rely on test results.

#### COMING UP

- 3/6 Bicameral Hill staff briefing on COVID-19
- 3/6 Senate HELP Minority and House E&C Majority staff briefing on COVID-19
- 3/6 Senate HELP Minority staff briefing on orphan drugs
- 3/6 House PSI Bipartisan staff briefing on ENDS
- 3/10 Meeting with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- 3/11 Senate HELP Minority staff briefing on YF-Vax Shortage
- 3/13 Senate HELP Minority staff briefing on clinical trial oversight
- 3/23 Senate HELP Bipartisan staff briefing on pharmacogenetics
- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/6/2020 4:00:02 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Friday, March 6, 2020

## TODAY

Sen. Roger Wicker (R-MS) introduced legislation to strengthen the use of patient-experience data within the benefit-risk framework for approval of new drugs.

Sen. Richard Burr (R-NC) and Rep. Diana DeGette (D-CO) introduced legislation to amend the Federal Food, Drug, and Cosmetic Act to provide for the regulation of in vitro clinical tests.

## FDA Briefings for Congress

- Bicameral Hill staff briefing on COVID-19
- Senate HELP Minority staff briefing on orphan drugs
- House PSI Bipartisan staff briefing on ENDS
- House E&C Bipartisan staff briefing on Cosmetic User Fees

## Outreaches

- FDA Announcement on Testing of Infant Rice Cereal

## Media

- Sen. Susan Collins (R-ME): In 2015, Martin Shkreli made the outrageous decision to raise Daraprim's price from \$13.50 to \$750 a pill. I chaired bipartisan hearings & authored a new law to help close the loophole Mr. Shkreli exploited. I'm glad FDA has approved a generic version of this lifesaving drug.
- Rep. Bill Pascrell (D-NJ): Earlier this week I called on @FTC @US\_FDA to crackdown on snakeoil salesman like this disgraced miscreant seeking to exploit public worry w/ worthless fraud elixirs to treat coronavirus.
- Rep. Grace Meng (D-NY): I'll be leading a letter calling on @US\_FDA to allow for NYC #coronavirus testing by private labs. Would help our city increase its capacity to test more people for the illness. Will also be calling on @CDCgov to provide more test kits to #NYC. Working w/@NYCMayor to get done.
- Sen. Maggie Hassan (D-NH): Update: It was long past time that @US\_FDA ban the cruel practice of using electric shock devices on people who experience disabilities. I'm glad that the FDA heeded our calls to end this.
- Sen. Michael Bennet (D-CO): Today I introduced the VALID Act with @SenatorBurr to create an FDA review process for diagnostic tests, supporting innovation while protecting patients and improving health outcomes for all Americans.
- Sen. James Lankford (R-OK): The Senate today approved additional funding to ensure @realDonaldTrump, @Mike\_Pence, @GovStitt & agencies like @CDCgov, @US\_FDA, & @StateDept have all they need to continue their efforts to prepare for and contain the spread of the #Coronavirus.
- Rep. Charlie Crist (D-FL): Florida only has 3 #coronavirus testing sites and with numbers rising, our state needs more. Sent letter to FDA & CDC calling on them to expedite process & work with private labs to secure more testing locations. We must use all resources to safeguard the health of our residents!
- Energy & Commerce GOP: Bipartisan committee leaders request briefing from @US\_FDA on reporting requirements for generic drugs

## COMING UP

- 3/9 Phone call with Sen. Patty Murray (D-WA) and Commissioner Hahn
- 3/9 House E&C Bipartisan staff briefing on Cosmetic User Fees
- 3/10 Phone call with Sen. Mitch McConnell (R-KY) and Commissioner Hahn
- 3/10 Meeting with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- 3/10 Meeting with Rep. Anna Eshoo (D-CA) and Commissioner Hahn
- 3/11 Senate HELP Minority staff briefing on YF-Vax Shortage
- 3/13 Senate HELP Minority staff briefing on clinical trial oversight
- 3/23 Senate HELP Bipartisan staff briefing on pharmacogenetics
- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/10/2020 4:15:09 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Tuesday, March 10, 2020

## TODAY

### FDA Briefings for Congress

- Senate HELP Bipartisan staff briefing on Current FDA Drug Supply Chain Authorities
- Senate HELP Minority and House E&C Majority staff briefing on Drug Supply Chain Language
- Phone call with Sen. Mitch McConnell (R-KY) and Commissioner Hahn
- Meeting with Sen. Jeff Merkley (D-OR) and Commissioner Hahn
- House E&C Bipartisan briefing on Continuous Manufacturing
- House E&C Bipartisan staff briefing on cosmetics
- Meeting with Rep. Anna Eshoo (D-CA) and Commissioner Hahn

### Outreaches

- FDA Warns Retailers, Manufacturers to Remove Unauthorized
- Coronavirus Update: Foreign Inspections

### Correspondence

- Sen. Blumenthal (D-CT) writes to urges FDA to continue taking action against fraudulent COVID-19 products
- Sen. Rick Scott (R-FL) writes with questions and concerns regarding lead in prenatal vitamins and its threat to expecting mothers

### Media

- Sen. Chris Coons (D-DE): Today, the ALS Caucus sent a letter to the Commissioner of the FDA calling for improvements to the clinical trial process for those with terminal illnesses, such as ALS. Individuals suffering from terminal illnesses deserve to have access to safe and promising treatments.
- Energy & Commerce Committee: NEWS: Health Subcommittee announces a markup of 13 bills to improve health outcomes for kids, strengthen benefits and coverage for Medicare and Medicaid beneficiaries and support the FDA's work overseeing food, drug, medical device and cosmetic safety.
- Rep. Debbie Mucarsel-Powell (D-FL): Every animal used in federal labs deserves a loving family to go home to. Euthanization is cruel and wasteful. I applaud the @US\_FDA for their new animal retirement policy and am very proud to be a cosponsor of the #AFTERAct.
- Energy & Commerce GOP: Bipartisan E&C members @repgregwalden, @frankpallone, @michaelcburgess, @repannaeshoo, @repguthrie & @repdianadegette ask @US\_FDA for briefing on drug & medical supply chain integrity & ask what additional resources are needed during #COVID19 outbreak
- Energy & Commerce Committee: Bipartisan E&C leaders request @US\_FDA briefing on #COVID19's impact on drug and medical supplies: "We would like to know how many manufacturers, distributors, and importers might be affected by supply chain issues as a result of the COVID-19 outbreak."
- Rep. Frank Pallone (D-NJ): I led a bipartisan group of @EnergyCommerce colleagues asking @US\_FDA about the potential impacts the #COVID19 outbreak could have on drug and medical supplies. You can read our letter to FDA here.
- Rep. Michael Burgess (R-TX): It is critical that we have a clear understanding of how @US\_FDA is working to prevent potential prescription drug shortages due to the #coronavirus.

- Rep. Sanford Bishop (D-GA): HAPPENING NOW: Watch as @AppropsDems & I discuss @USDA & @FDA's budget request for FY2021 w/ @SecretarySonny.
- Rep. Anna Eshoo (D-CA): The Coronavirus has already caused one drug shortage and it's unclear if there are more to come. I wrote to @US\_FDA to ask questions about how the agency is preparing. Read the letter below.

#### COMING UP

- 3/12 Senate Bipartisan member briefing on COVID-19
- 3/12 Senate HELP Minority briefing on device shortages
- 3/12 Phone call with Sen. James Lankford (R-OK) and Commissioner Hahn
- 3/12 House Bipartisan member briefing on COVID-19
- 3/13 Bicameral Hill staff briefing on COVID-19
- 3/13 Senate HELP Minority staff briefing on clinical trial oversight
- 3/13 House E&C Bipartisan staff briefing on transition
- 3/13 House Ag and E&C Minority briefing on CBD
- 3/23 Senate HELP Bipartisan staff briefing on pharmacogenetics
- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn
- 3/26 Meeting between Sen. Richard Durbin (D-IL) and Commissioner Hahn

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/12/2020 3:39:47 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Thursday, March 12, 2020

## TODAY

Rep. Nita Lowey (D-NY) introduced legislation to make emergency supplemental appropriations for the fiscal year ending September 30, 2020.

## FDA Briefings for Congress

- Senate Bipartisan member briefing on COVID-19
- Senate HELP Minority briefing on device shortages
- House Bipartisan member briefing on COVID-19
- Phone call between Rep. Michael Burgess (R-TX) and Dr. Jeff Shuren

## Media

- Rep. Greg Walden (R-OR): Yesterday, I sent a letter to the @US\_FDA requesting a briefing on the coronavirus' impact on drug and medical supplies. It is important we have all the facts and are prepared for what lies ahead.
- Rep. Frank Pallone (D-NJ): The @EnergyCommerce Health Subcommittee voted in favor of my bill to empower @US\_FDA to regulate cosmetics today. This update is long overdue and will protect consumers from harmful products by allowing, among other things, FDA to review ingredients and recall harmful products.
- Rep. Max Rose (D-NY): Political differences should never impact our response to an emergency like this, which is why I joined my Republican colleague @RepTomReed in urging @CDCgov and @US\_FDA to approve these tests. Now it's time to make sure bureaucratic red tape doesn't slow us down either.
- Rep. Max Rose (D-NY): We need fully automated #coronavirus testing in New York, but so far not a single NY laboratory has been approved. Today I pressed @CDCgov and @US\_FDA to commit publicly to making this a priority, and I promised I'll keep contacting their office every single day until it happens.
- Sen. Marco Rubio (R-FL): Expected executive order by @POTUS on medical supplies is a very strong first step toward increasing domestic production by enforcing Buy American requirements for pharmaceuticals & medical supplies & fast-tracking @US\_FDA approval.
- Sen. Marsha Blackburn (R-TN): "The coronavirus has sounded the alarm over America's dependence on China and India for producing prescription medications. The FDA announced in February that it had a shortage of one drug used to treat patients with coronavirus."
- Sen. Bill Cassidy (R-LA): Members of our community have contracted COVID-19, and it is likely more cases will emerge over the next week. There are steps we can take and are taking to limit the impact of the virus.
- Senate Ag Republicans: Roberts: Established in 1986, USDA, EPA, and FDA each serve roles in the regulation of the products of modern ag biotechnology through the Coordinated Framework. The key word here is \*coordinated\*
- Senate Ag Republicans: Roberts: In 2017, FDA issued draft guidance addressing animals w altered DNA through new tech. In 2019, APHIS published a proposed rule to update & reduce reg burdens for tech developers of advanced genetic engineering, such as genome editing. This rule is under review at OMB.
- Senate Ag Republicans: Roberts: USDA, along with EPA and FDA, have a responsibility to establish policies that are: science-based, timely, transparent, coordinated, functional for the industries that rely upon them.

## COMING UP

- 3/13 Bicameral Hill staff briefing on COVID-19

- 3/13 Senate HELP Minority staff briefing on clinical trial oversight
- 3/13 House E&C Bipartisan staff briefing on transition
- 3/13 House Ag and E&C Minority staff briefing on CBD
- 3/18 Sen. Tina Smith (D-MN) staff briefing on transition
- 3/20 House E&C Bipartisan staff briefing on drug and device supply chain vulnerabilities and shortages due to COVID-19
- 3/23 Senate HELP Bipartisan staff briefing on pharmacogenetics
- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn
- 3/26 Meeting between Sen. Richard Durbin (D-IL) and Commissioner Hahn

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/13/2020 10:04:05 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: FDA Hotline Information

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**From:** Meister, Karen G  
**Sent:** Thursday, March 12, 2020 5:01 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: FDA Hotline Information

(b)(5) ..... Thank you!

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**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Thursday, March 12, 2020 4:59 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** FDA Hotline Information

FDA's Office of Legislation would like to flag that FDA's hotline (1-888-INFO-FDA) is available 24 hours a day for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples. We also encourage labs to reach out at [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov) with any questions related to diagnostic development. We hope this will be useful to your constituent developers.

You may also be interested in our [COVID-19 Frequently Asked Questions](#) page, which contains information on vaccines, diagnostic tests, drugs, medical devices, food and other products FDA regulates.

Thank you and please don't hesitate to contact Lauren Paulos at [lauren.paulos@fda.hhs.gov](mailto:lauren.paulos@fda.hhs.gov) if you have any questions or need information as this situation develops.



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**Sent:** 3/16/2020 7:53:14 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

Good morning,

No biggie! (b)(6) I know this is cross-cutting, so it just makes more sense for it to be an issue and not based on center so there can be one POC. I can definitely fill in when you aren't available.

Erica

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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 7:38 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

That's fine with me. Erica- I appreciate your sending out the e-mail on Friday while I was on SL!

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, March 13, 2020 1:49 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Re: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

Hi guys,

Since Chris has been sending out the majority of the COVID emails, it may be better to let him manage all of them, instead of us doing it piecemeal. We should probably treat it as an issue and not do it based on Center. What are your thoughts?

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**

Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov

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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Date:** March 13, 2020 at 1:25:41 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

I also sent this to ASTHO, NGA, NAACHO, and NCSL. Thanks! Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Friday, March 13, 2020 1:23 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

Good afternoon-

FDA's Intergovernmental Affairs (IGA) team wanted to share with you the following press release on actions related to New York State Department of Health (NYSDOH) and the third EUA granted for a diagnostic test during the COVID-19 outbreak to Roche Molecular Systems, Inc. Please contact Taylor Price for further information regarding this announcement.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at IGA@fda.hhs.gov.

Best,  
Chris

## **Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization diagnostic**

Yesterday, the U.S. Food and Drug Administration took two significant actions in the agency's ongoing and aggressive commitment to address the coronavirus outbreak (COVID19).

First, the agency issued enforcement discretion and is not objecting to the New York State Department of Health (NYSDOH) authorizing certain laboratories in New York to begin patient testing after validating their tests and notifying the NYSDOH. Under NYSDOH's approach, laboratories will provide validation data to NYSDOH within 15 days in lieu of pursuing an Emergency Use Authorization (EUA) with FDA.

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The FDA is granting this flexibility to NYSDOH based on the urgent public health need for additional testing capacity. The FDA weighed several factors in this decision, including that the NYSDOH has a long-established framework in place for oversight of laboratory developed tests in New York State. The FDA had also previously accredited Wadsworth be a third-party reviewer for certain molecular tests.

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**Additional Resources:**

- [Novel Coronavirus](#)
- [Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency - Immediately in Effect](#)  
[Guidance for Clinical Laboratories and Food and Drug Administration Staff](#)

**Christopher C. Campbell, M.A.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (240) 338-7449**  
**[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)**



---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/16/2020 8:13:27 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: test reagent supply at the Oklahoma PHL

Hey- I just tried calling you. Give me a call. C

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 8:07 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: test reagent supply at the Oklahoma PHL

(b)(5)

Erica

---

**From:** Samuel T Dunn <TerryD@health.ok.gov>  
**Sent:** Saturday, March 14, 2020 8:05 AM  
**To:** IGA <IGA@fda.hhs.gov>; Travis Kirkpatrick <TravisK@health.ok.gov>  
**Subject:** test reagent supply at the Oklahoma PHL

The Oklahoma State Public Health Laboratory is running the CDC coronavirus test and has reagents on-hand for about 400 extractions. We just ordered more reagents from CDC IRR – including RNA extraction kits -sufficient for 500 specimens (maximum allowable in the ordering system) - which seems to be the most limiting reagent for us. The number of specimens being submitted to our lab for testing is steadily increasing and there is much pressure to loosen patient testing criteria –this will likely mean that we will run out of reagents before our order from IRR arrives. This makes it very difficult to make any strategic decisions regarding testing. My commissioner has ask me to use this contact to inquire as to what measures can be taken to massively increase supply of reagents to our laboratory. We have greater capacity for testing (~200 tests per day) but if we ramped-up testing to that capacity, given the current supply of reagents, we would be unable to test in about 3 days. Your response would be greatly appreciated.

S. Terence Dunn, PhD  
Director, Public Health Laboratory  
Oklahoma State Department of Health  
1000 N.E. 10th Street  
Oklahoma City, OK 73117-1207  
Email: TerryD@health.ok.gov  
Fax: 405-271-4850; Tel: 405-271-5070

Sent from Mail for Windows 10

---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/16/2020 8:39:23 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6b3e8bf491fee037f-KMEISTER]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: test reagent supply at the Oklahoma PHL

Karen- per our conversation. C

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 8:07 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: test reagent supply at the Oklahoma PHL

(b)(5)

Erica

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Director, Public Health Laboratory  
Oklahoma State Department of Health  
1000 N.E. 10th Street  
Oklahoma City, OK 73117-1207

Email: [TerryD@health.ok.gov](mailto:TerryD@health.ok.gov)

Fax: 405-271-4850; Tel: 405-271-5070

Sent from Mail for Windows 10

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**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/16/2020 9:39:26 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: test reagent supply at the Oklahoma PHL

Good info. Thanks for sharing!

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 9:39 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: test reagent supply at the Oklahoma PHL

Thanks. I will use this for future lab questions.

Erica

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 9:33 AM  
**To:** TerryD@health.ok.gov  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: test reagent supply at the Oklahoma PHL

Hi Dr. Dunn-

Thank you for reaching out. I recently started as the Acting Director for Intergovernmental Affairs. Sorry for the delay in this response given the urgent nature.

FDA's hotline (1-888-INFO-FDA) is available 24 hours a day for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples.

Hope this is helpful. Please let me know if you have further questions. I am reachable at any of the numbers below. I am also copying Erica White on our team who handles device issues.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs*



Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office

(b)(6)

work cell)

personal cell- I will call you back on work phone)

---

**From:** Samuel T Dunn <TerryD@health.ok.gov>  
**Sent:** Saturday, March 14, 2020 8:05 AM  
**To:** IGA <IGA@fda.hhs.gov>; Travis Kirkpatrick <TravisK@health.ok.gov>  
**Subject:** test reagent supply at the Oklahoma PHL

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**Sent:** 3/16/2020 9:42:02 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: test reagent supply at the Oklahoma PHL

Thank you. That is a big help to me.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 9:42 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: test reagent supply at the Oklahoma PHL

sure

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 9:40 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: test reagent supply at the Oklahoma PHL

Thanks Erica. Would you please put this inquiry on the tracker?

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, March 16, 2020 9:39 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: test reagent supply at the Oklahoma PHL

Thanks. I will use this for future lab questions.

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**Sent:** Monday, March 16, 2020 9:33 AM  
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(301) 796-8916 office*

**(b)(6)**

*work cell)*

*personal cell- I will call you back on work phone)*

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**Sent:** 3/17/2020 11:14:08 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** RE: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

nope

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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 11:12 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

Hi- Did Karen ask you to put this inquiry from Indiana in the SP tracker? C

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 11:09 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

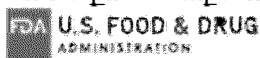
Yes I did. Can you close out in tracker if it's in there please?

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 11:07 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

Hi- Just checking if you ever closed the loop with IN on this? Thx C

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



**From:** Deborah Hohlt <debbie@indianagr.com>

**Sent:** Friday, March 13, 2020 5:14 PM

**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>

**Subject:** Re: Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization Diagnostic

Have an urgent Indiana question. Please call me ASAP.

Debbie Hohlt

(b)(6)

Thanks

On Fri, Mar 13, 2020 at 1:23 PM Campbell, Christopher <Christopher.Campbell@fda.hhs.gov> wrote:

Good afternoon-

FDA's Intergovernmental Affairs (IGA) team wanted to share with you the following press release on actions related to New York State Department of Health (NYSDOH) and the third EUA granted for a diagnostic test during the COVID-19 outbreak to Roche Molecular Systems, Inc. Please contact Taylor Price for further information regarding this announcement.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at IGA@fda.hhs.gov.

Best,

Chris

## **Coronavirus (COVID-19) Update: FDA gives flexibility to New York State Department of Health, FDA issues Emergency Use Authorization diagnostic**

Yesterday, the U.S. Food and Drug Administration took two significant actions in the agency's ongoing and aggressive commitment to address the coronavirus outbreak (COVID19).

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Christopher C. Campbell, M.A.

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (240) 338-7449

[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)



--

Debbie Hohlt  
202-445-8999

---

**Sent:** 3/17/2020 1:48:22 PM  
**To:** Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**Subject:** RE: Sterigenics Atlanta Georgia Sterilization Facility

So I am cold calling Cobb County and asking them to talk with us today about (b)(4) at Sterigenics correct?

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 17, 2020 at 1:43:29 PM EDT  
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Sterigenics Atlanta Georgia Sterilization Facility

Erica-

Reach out to Cobb County by telephone and set up a time for us to call.

Please include me too.

Suzanne, besides you, who else should be included on the call?

Erica can send webex number.

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 1:40 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** FW: Sterigenics Atlanta Georgia Sterilization Facility

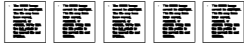
Fyi, (b)(5)

**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

Cel: (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:** Macnabb, Philip <PMacnabb@sterigenics.com>  
**Sent:** Tuesday, March 17, 2020 1:33 PM  
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>  
**Subject:** RE: Sterigenics Atlanta Georgia Sterilization Facility

Suzanne

Thanks again for the note.

(b)(4)

(b)(4)

(b)(4)

If your team is open to that, please reach out

to:

Rob Hosack, Cobb County Manager  
(770) 528-2600  
Robert.Hosack@cobbcounty.org

And

Bob Ott, Cobb County District 2 Commissioner  
(770) 528-3316  
Bob.ott@cobbcounty.org

Thanks again for any assistance and please let me know if you have any questions or would like to discuss further.



**Philip Macnabb**

**President**

Sterigenics, A Sotera Health company

2015 Spring Rd, Suite 650

Oak Brook, IL 60523

pmacnabb@sterigenics.com

www.sterigenics.com

O: (630) 928-1733

---

**From:** Schwartz, Suzanne [mailto:Suzanne.Schwartz@fda.hhs.gov]  
**Sent:** Tuesday, March 17, 2020 10:17 AM  
**To:** Macnabb, Philip; CDRH All Hazards Readiness Response and Cybersecurity  
**Cc:** Ross, Aftin; Claverie, Elizabeth F; Ricci, Linda J  
**Subject:** [EXTERNAL] RE: Sterigenics Atlanta Georgia Sterilization Facility

**CAUTION:** This email originated from outside of the organization. **DO NOT CLICK** links or attachments unless you recognize the sender and know the content is safe.

Mr. Macnabb,

In our efforts to expediently address your request and work on multiple COVID-19 concerns, I am not sure that we circled back with you yesterday!

(b)(5)

(b)(5)

We will keep you posted.

Best,

Suzanne

**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:** Macnabb, Philip <PMacnabb@sterigenics.com>  
**Sent:** Monday, March 16, 2020 11:32 AM  
**To:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>  
**Subject:** Sterigenics Atlanta Georgia Sterilization Facility

CDRH Team

I am writing to you at the suggestion of Elizabeth Claverie-Williams, who I am also copying here. I wanted to

(b)(4)

If you are in agreement, I request that you contact Candice Brocce, Director of Communications for Governor Kemp's office, to discuss. She can be reached on her cell phone at (b)(4) I can alert her to your call.

I am also available to discuss further with you if you would like more details around this situation.

Thank you

**Philip Macnabb**  
**President**

Sterigenics, A Sotera Health company

2015 Spring Rd, Suite 650

Oak Brook, IL 60523

[pmacnabb@sterigenics.com](mailto:pmacnabb@sterigenics.com)

[www.sterigenics.com](http://www.sterigenics.com)

O: (630) 928-1733

---

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---

**Sent:** 3/17/2020 3:12:53 PM  
**To:** Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**CC:** Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]  
**Subject:** RE: Sterigenics Atlanta Georgia Sterilization Facility

Just spoke with Commissioner Ott's assistant and she going to try and arrange a call with . We are not sure about timing

---

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Sent:** Tuesday, March 17, 2020 3:02 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** FW: Sterigenics Atlanta Georgia Sterilization Facility

I know that Erica just tried calling and the Cobb County officials were not available.  
Please see note below from Sterigenics.  
Shall we just send over the note with whatever edits we feel is appropriate?

suzanne

**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](mailto: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:** Macnabb, Philip <PMacnabb@sterigenics.com>  
**Sent:** Tuesday, March 17, 2020 2:53 PM  
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>  
**Subject:** RE: Sterigenics Atlanta Georgia Sterilization Facility

Sorry to bombard you with notes as I know you have several priorities, but this one is mine right now, and I think our joint one in the interest of public health. After speaking again with the county they are looking for a note from you that they can share with leadership regarding the importance of the facility. Something like the following:

Mr. Rob Hosack  
Cobb County Manager  
100 Cherokee Street  
Marietta, GA 30090-7000

Dear Mr. Hosack:

As you are aware, our nation's health care system is facing a critical challenge in responding to the Covid-19 pandemic. In meeting this challenge it is critically important that our front line health care providers have an adequate supply of personal protective equipment (PPE).

(b)(4)

If you have any questions, please do not hesitate to contact me. Thank you.

I don't know if you see that as a possibility but am passing along their request. Thanks again for any assistance.

**Philip Macnabb**

**President**

Sterigenics, A Sotera Health company  
2015 Spring Rd, Suite 650  
Oak Brook, IL 60523  
pmacnabb@sterigenics.com  
www.sterigenics.com  
O: (630) 928-1733



---

**From:** Schwartz, Suzanne [mailto:Suzanne.Schwartz@fda.hhs.gov]  
**Sent:** Tuesday, March 17, 2020 12:38 PM  
**To:** Macnabb, Philip; CDRH All Hazards Readiness Response and Cybersecurity  
**Cc:** Ross, Aftin; Claverie, Elizabeth F; Ricci, Linda J  
**Subject:** [EXTERNAL] RE: Sterigenics Atlanta Georgia Sterilization Facility

**CAUTION:** This email originated from outside of the organization. **DO NOT CLICK** links or attachments unless you recognize the sender and know the content is safe.

Thank you for this contact. We will follow through.

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

Cel: (b)(6)

[Suzanne.Schwartz@fda.hhs.gov](mailto: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:** Macnabb, Philip <PMacnabb@sterigenics.com>

**Sent:** Tuesday, March 17, 2020 1:33 PM

**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>

**Subject:** RE: Sterigenics Atlanta Georgia Sterilization Facility

Suzanne

Thanks again for the note.

(b)(4)

(b)(4)

(b)(4)

if your team is open to that, please reach out to:

Rob Hosack, Cobb County Manager

(770) 528-2600

[Robert.Hosack@cobbcounty.org](mailto:Robert.Hosack@cobbcounty.org)

And

Bob Ott, Cobb County District 2 Commissioner

(770) 528-3316

[Bob.ott@cobbcounty.org](mailto:Bob.ott@cobbcounty.org)

Thanks again for any assistance and please let me know if you have any questions or would like to discuss further.

**Philip Macnabb**

**President**

Sterigenics, A Sotera Health company

2015 Spring Rd, Suite 650

Oak Brook, IL 60523

[pmacnabb@sterigenics.com](mailto:pmacnabb@sterigenics.com)

[www.sterigenics.com](http://www.sterigenics.com)

O: (630) 928-1733



---

**From:** Schwartz, Suzanne [mailto:Suzanne.Schwartz@fda.hhs.gov]  
**Sent:** Tuesday, March 17, 2020 10:17 AM  
**To:** Macnabb, Philip; CDRH All Hazards Readiness Response and Cybersecurity  
**Cc:** Ross, Aftin; Claverie, Elizabeth F; Ricci, Linda J  
**Subject:** [EXTERNAL] RE: Sterigenics Atlanta Georgia Sterilization Facility

**CAUTION:** This email originated from outside of the organization. **DO NOT CLICK** links or attachments unless you recognize the sender and know the content is safe.

Mr. Macnabb,

In our efforts to expediently address your request and work on multiple COVID-19 concerns, I am not sure that we circled back with you yesterday;

(b)(5)

(b)(5)

We will keep you posted.

Best,  
Suzanne

**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:** Macnabb, Philip <PMacnabb@sterigenics.com>  
**Sent:** Monday, March 16, 2020 11:32 AM  
**To:** CDRH All Hazards Readiness Response and Cybersecurity <cdrharc@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Claverie, Elizabeth F <Elizabeth.Claverie@fda.hhs.gov>  
**Subject:** Sterigenics Atlanta Georgia Sterilization Facility

CDRH Team

I am writing to you at the suggestion of Elizabeth Claverie-Williams, who I am also copying here.

(b)(4)

(b)(4)

If you are in agreement, I request that you contact Candice Brocche, Director of Communications for Governor Kemp's office, to discuss. She can be reached on her cell phone at (b)(6). I can alert her to your call.

I am also available to discuss further with you if you would like more details around this situation.

Thank you

**Philip Macnabb**

**President**

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[www.sterigenics.com](http://www.sterigenics.com)

O: (630) 928-1733



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---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/18/2020 5:23:33 PM  
**To:** Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]  
**CC:** Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** URGENT: Letter to Cobb County re: Sterigenics  
**Attachments:** Cobb Co Sterigenics Clean 5 pm.docx

Attached is draft letter for your review. Please advise of next steps re: clearance. We addressed to Chairman of Cobb County with cc's to governor and EPA Division and provided for Commissioner signature. Obviously let us know if we should change to address to Governor or EPA head.

Does this have to go thru EXEC Sec because it's a commissioner signature? We will transmit final by email. I have Akeisha Borwn to be on standby to put in final type. Please let me know if we want to get this out tonight so I can advise her whether to standby for final type.

Thank you!

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office*

**(b)(6)** (work cell)  
(personal cell- I will call you back on work phone)

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/19/2020 7:38:07 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** Fwd: Sterigenics letter  
**Attachments:** To Erika Cobb Co Sterigenics final type 9 pm (005).docx

Should have cc'ed you on this.

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 18, 2020 at 9:43:00 PM EDT  
**To:** Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** Sterigenics letter

Hi Erika-

Attached is final letter for commissioner signature. Track changes is still on if anyone wants to make changes. Akeisha Brown just finished final type and we told her we would let her know in the AM if there are further changes or if it's finalized and we can proceed to distribute. Presume you will send to ExecSec?

Thanks for your prompt attention and support in getting this out.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office  
(b)(6) (work cell)  
(b)(6) (personal cell- I will call you back on work phone)*

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/19/2020 9:09:36 AM  
**To:** Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]  
**Subject:** Fwd: GA Governor letter  
**Attachments:** Sterigenics Cobb Co ltr upddd.docx; Sterigenics Cobb Co ltr.pdf

(b)(5) OES should mail hard copies please

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

---

**From:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>  
**Date:** March 19, 2020 at 8:53:38 AM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: GA Governor letter

Signed letter attached in both word and pdf. What are next steps as far as distribution? Should OES plan to email hard copies per normal process?

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 19, 2020 8:20 AM  
**To:** Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** Re: GA Governor letter

Occ cleared (b)(5)

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs

Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

---

**From:** Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Date:** March 19, 2020 at 8:10:44 AM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>, Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>  
**Cc:** Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>, Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** GA Governor letter

Hi all,

To keep this moving this morning:

Karen – can you confirm OCC has cleared this?

Emily – can you clear this for ethics?

Once that is done, Lindsay – can you secure a Commissioner signature on this?

Thanks.  
Erika

**Erika Anderson**

Office of Policy, Legislation, and International Affairs  
U.S. Food and Drug Administration  
Tel: 240-402-4893  
erika.anderson@fda.hhs.gov



---

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/19/2020 3:54:21 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Thursday, March 19, 2020

## TODAY

### FDA Briefings for Congress

- Senate HELP Bipartisan staff briefing on device shortages
- Senate HELP Bipartisan & Sen. McConnell (R-KY) staff briefing on food shortages
- Senate HELP Bipartisan and House E&C Bipartisan staff briefing on FDA Shortage A-19 on supply chain/risk management plans
- House E&C Bipartisan staff briefing on drug and device supply chain vulnerabilities and shortages due to COVID-19
- Phone call between Rep. Jeff Fortenberry (R-NE) and Commissioner Hahn

### Outreaches

- FDA Issues Final Guidance: "Submission of Plans for Cigarette Packages and Cigarette Advertisement"
- FDA Domestic Tobacco Inspections

### Media

- Rep. Justin Amash (I-MI): This is a tale of two approaches: South Korea's government allowed the private sector to act quickly to develop testing. Our government allowed the FDA to block private sector efforts, precisely when they were needed most.
- Rep. Ron Kind (D-WI): In order to combat the spread of #COVID19 we have to be able to test people & get the results quickly. Right now, hospitals across WI are facing extreme challenges because they don't have enough supplies to test patients. This morning I led the WI delegation on a letter to the @US\_FDA requesting more testing supplies to be sent to our state immediately so health care providers can continue to do their jobs without delay.
- Rep. Ron Estes (R-KS): This morning's #coronavirus briefing was encouraging as the FDA, scientists, medical professionals, & innovators are working around the clock to develop & approve safe & effective anti-viral treatments. This is only possible because of unleashed American ingenuity. #InItTogether
- Rep. Bill Pascrell (D-NJ): On March 3 I called on @US\_FDA @FTC to crack down on this disgraced swindler Bakker for selling a fake coronavirus cure and they agreed. It looks like more work needs to be done to stop his sinister schemes.
- Rep. Mike Gallagher (R-WI): Wisconsin is ready to expand its testing capacity, but shortages of reagents and other supplies are greatly limiting our ability to do so. Today I joined @RepRonKind & the delegation in calling on the FDA to work with @DHSWI to get WI hospitals & labs the supplies they need ASAP.
- Rep. Mike Gallagher (R-WI): This is why my colleagues and I are calling on FDA to expedite supplies to WI labs and hospitals. Ultimately, the more flexibility the FDA provides testing facilities and the more supplies we can provide/support we can give manufacturers, the faster testing can be done.
- Sen. Tammy Baldwin (D-WI): Wisconsin hospitals are currently facing a dire shortage of #coronavirus testing supplies. I've joined the entire #WI Congressional delegation in calling on @US\_FDA to get Wisconsin the medical supplies they need to test patients right now for COVID-19.

### COMING UP

- 3/20 Bicameral Hill staff briefing on COVID-19
- 3/20 Phone call with Sen. Pat Toomey (R-PA) and Dr. Jeff Shuren
- 3/23 Senate HELP Bipartisan staff briefing on pharmacogenetics

- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn

*The Office of Legislation (OL), an office within the Office of Policy, Legislation, and International Affairs (OPLIA), directs and manages FDA's engagement with Congress. Please feel free to contact OL staff directly or via 301-796-8900 or [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov). For matters specific to the congressional budget and appropriations process, please contact the Office of Congressional Appropriations (OCA) at 240-402-2718 or [jenna.zembower@fda.hhs.gov](mailto:jenna.zembower@fda.hhs.gov).*

---

**From:** Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]  
**Sent:** 3/19/2020 8:26:40 PM  
**To:** Gras, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=896294988ddc451f93b1073f119943af-Ruth.Gras]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Norris, Gary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dc19fae0c7d44332a71e1ff7aa2cefbc-Gary.Norris]  
**Subject:** RE: IGA Email Outreach of Announcement re: Blood Supply and Food Workers

Thank you so much to everyone for so quickly jumping on this and getting it done. This will truly have an impact on the public health.

Lorrie has put the TPs through JIC/OCC clearance for tomorrow morning. Please let me know what else you need from CBER in terms of the script or other logistics for tomorrow.

---

**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Thursday, March 19, 2020 8:11 PM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Subject:** IGA Email Outreach of Announcement re: Blood Supply and Food Workers

The IGA email outreach for this is complete. A copy of an example email is attached. Emails went to:

- **All State Governors' Offices – Federal/State Directors**
- Personal emails went to those in Ohio, New York State, and Maryland
- **All State AG offices – Senior Contacts (mostly Chiefs of Staff)**
- No personal emails were sent for AG offices
- **All State Health Dept Contacts**
- Personal emails went to those in Ohio, New York State, and Maryland
- **Top 300 Mayors' Offices – only those with Federal Affairs Directors**
- Personal emails went to Fed Affairs Directors for NYC and San Francisco
- **Also, personal emails went to:** health officials in the seven SF Bay Area Counties under the SIP Order, plus in PH officials in Chicago, IL and Fishers, IN

**NEXT:** All of these folks should be invited to tomorrow's call. I will coordinate directly with Gary Norris on determining the appropriate/needed email lists.

---

**From:** Alexander, Nicholas  
**Sent:** Thursday, March 19, 2020 3:11 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Boon, Caitlin <Caitlin.Boon@fda.hhs.gov>; Tierney, Julia

<Julia.Tierney@fda.hhs.gov>

**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

**Subject:** Draft of note re: blood donation and food processors

**Importance:** High

The following is based on the JIC cleared messages related to blood donation and food processors. IGA will be sending to Governors, Attorneys General, State Health Department Leads, and Major City Mayors. Take a look and provide any feedback ASAP as this will go out with the blood donation PR.

Dear State/Local Leader:

We want to bring to your attention two issues of critical importance related to implementation of social distancing, travel restrictions, and other measures put into place to respond to the COVID-19 pandemic.

**Blood Donation:**

There has been a dramatic reduction in blood donation, including cancellation of blood drives, during the COVID-19 pandemic. We have also heard concerns about collections of source plasma, which is a critical ingredient in biologics used to treat many serious diseases, and is also currently being used to develop potential treatments for COVID-19 infections.

**Food Processing Workers:**

We are aware of a recently reported incident where food processing facility workers were stopped on the way to their jobs due to curfew/shelter-in-place orders.

**As you develop your local response to the COVID-19 pandemic, including any planned or potential travel restrictions, we urge you to consider the continued operation of blood and source plasma collection centers, including travel to the centers by individuals intending to donate. We also urge you to consider ways to enable food and beverage employees, who are considered part of a critical business sector, to make it to their workplace.**

**(See also recent guidance from the Director of the Department of Homeland Security's Cybersecurity and Infrastructure Security Agency (CISA), entitled *MEMORANDUM ON IDENTIFICATION OF ESSENTIAL CRITICAL INFRASTRUCTURE WORKERS DURING COVID-19 RESPONSE*.)**

We would appreciate your help, within your respective jurisdictions, to ensure awareness, coordination and communication with appropriate law enforcement agencies, state/local emergency operation centers, and with other stakeholders, so that those operating blood and plasma collection centers as well as donors – who are contributing immeasurably to the country's preparedness – can travel to and from blood and source plasma collection centers. We also hope that you will reiterate our messages in the attached press release [TO BE ATTCHED] about the importance of blood and plasma donation and the measures that are being taken so that individuals can donate safely during this critical time. You will receive more information about a state/local call on this issue shortly.

We would also appreciate your assistance in ensuring that the same awareness, coordination and communication happens with the appropriate state/local agencies so that human and animal food workers – who are part of the critical infrastructure – will be allowed to travel to and from their jobs. We are also working with food industry stakeholders to ensure their food workers have appropriate identification.

If you have any questions, please contact FDA's Intergovernmental Affairs team at IGA@fda.hhs.gov.

-- Nick

**Nick Alexander, J.D.**

*Senior Advisor to the Deputy Commissioner*

**Office of Policy, Legislation, and International Affairs**

**Office of the Commissioner**



**U.S. Food and Drug Administration**

Direct: 301-796-8893 Mobile: (b)(6)  
nicholas.alexander@fda.hhs.gov



---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/20/2020 4:58:11 PM  
**To:** ken.Johnston@dph.sbcounty.gov  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** FW: FDA Policy Update Re: COVID-19 Test Development and Distribution  
**Attachments:** HRT Rapid Test.jpg; HRT Certificate.jpg; HRT Results.jpg; HRT Rapid Test.jpg

The following information does not seem to mention internationally developed tests. We are trying to get more information on that. In the meantime, however, the following link may be helpful if you haven't already seen it.

FDA's hotline (1-888-INFO-FDA) is available 24 hours a day for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples. We also encourage labs to reach out at (b)(6)@fda.hhs.gov with any questions related to diagnostic development. Also, see frequently asked questions: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2>.

Thank you for reaching out. Please don't hesitate to reach out to me at any of the numbers below. Stay safe.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office*

(b)(6) (work cell)  
(b)(6) (personal cell- I will call you back on work phone)

---

**From:** Johnston, Ken - PH <(b)(6)>  
**Sent:** Friday, March 20, 2020 3:06 PM  
**To:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
**Subject:** FDA Policy Update Re: COVID-19 Test Development and Distribution

Hello Ms. Caccamo,

I have a question about the updated FDA policy on March 16 regarding distribution of new commercially-developed COVID-19 tests and the recommendations for developing serological tests prior to the FDA granting an EUA.

Does this apply to tests that are developed internationally? Or do you have additional guidance for internationally developed tests?

I have attached an example for your reference. Thank you in advance for any guidance you can provide.

**Ken Johnston**  
Quality and Compliance Officer  
Department of Public Health

Phone: 909-387-6304  
351 N. Mt. View Avenue  
San Bernardino CA 92415



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---

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/23/2020 4:19:38 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Monday, March 23, 2020

## TODAY

Sen. Mitch McConnell (R-KY) introduced legislation to provide emergency assistance and health care response for individuals, families, and businesses affected by the 2020 coronavirus pandemic.

Rep. Frederica Wilson (D-FL) introduced legislation to provide for coverage (without cost sharing or utilization management requirements) under group health plans and individual and group health insurance coverage of testing for COVID-19.

## FDA Briefings for Congress

- March 20: Senate Finance Bipartisan staff briefing on alcohol excise tax
- March 20: Remdesivir briefing for Rep. John Rose (R-TN)
- March 21: Phone call between Sen. Ron Johnson (R-WI) and Commissioner Hahn
- March 22: House E&C Majority staff briefing on volume language
- Phone call with Sen. Richard Durbin (D-IL) and Commissioner Hahn
- Phone call between Sen. Tammy Baldwin (D-WI) and Dr. Jeff Shuren
- Senate HELP Minority and Sen. Dianne Feinstein (D-CA) staff briefing on marijuana research

## Outreaches

- March 21: Coronavirus (COVID-19) Update: FDA Issues first Emergency Use Authorization for Point of Care Diagnostic
- March 22: Coronavirus (COVID-19) Update: FDA provides update on patient access to certain REMS drugs
- March 22: Coronavirus (COVID-19) Update: FDA Continues to Facilitate Access to Crucial Medical Products, Including Ventilators
- Statement from FDA Principal Deputy Commissioner Amy Abernethy, M.D., Ph.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the transition of insulin and certain other biologic drugs to a different regulatory pathway
- FDA's Message to Patients With Cancer and Health Care Providers About COVID-19

## Media

- Rep. Tom Emmer (R-MN): Thanks to @US\_FDA for your quick approval of this potentially life-saving test!
- Rep. Grace Meng (D-NY): I'm continuing to look for opportunities to bring #PPE into the States to protect health care workers & patients. I know there are manufacturers globally that can end the #PPE shortage. @US\_FDA must expedite its approval process for #PPE to help those working to combat #COVID19
- E&C GOP: Fake #COVID19 tests have been confiscated @US\_FDA needs authority to destroy imported fake medical devices, including tests @repguthrie's bipartisan bill will give that authority. Read more about bill that needs to be in #COVID19 aid package
- Rep. Martha Roby (R-AL): Any labs or providers in #AL02 that are having trouble obtaining testing supplies for #COVID19 should call @US\_FDA hotline at 1-888-463-6332 which is available 24 hours a day. Local health departments can also call or work w/ state officials to make requests w/ @fema or @PHEgov.

## COMING UP

- 3/25 Rep. Steve Stivers (R-OH) member briefing on fraudulent dietary supplements
- 3/25 Phone call with Rep. Mark Pocan (D-WI) and Commissioner Hahn
- 3/26 House E&C Bipartisan staff briefing on cosmetics

*The Office of Legislation (OL), an office within the Office of Policy, Legislation, and International Affairs (OPLIA), directs and manages FDA's engagement with Congress. Please feel free to contact OL staff directly or via 301-796-8900 or [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov). For matters specific to the congressional budget and appropriations process, please contact the Office of Congressional Appropriations (OCA) at 240-402-2718 or [jenna.zembower@fda.hhs.gov](mailto:jenna.zembower@fda.hhs.gov).*

---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/24/2020 8:33:54 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Utah Question: Hydroxychloroquine / chloroquine shortage

Fyi c

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** Campbell, Christopher  
**Sent:** Friday, March 20, 2020 2:52 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Bormel, Frances Gail <Frances.Bormel@fda.hhs.gov>  
**Subject:** FW: Utah Question: Hydroxychloroquine / chloroquine shortage

Caitlin- Here is the first of many (I'm sure) questions concerning Hydroxychloroquine. Thanks for your assistance in getting us a response!

Copying Gail Bormel in CDER/Compounding for her situational awareness.

-Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** IGA <IGA@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 2:48 PM  
**To:** Jennifer Zaelit <jzaelit@utah.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Hydroxychloroquine / chloroquine shortage

Dear Jennifer-

On behalf of FDA's Intergovernmental Affairs (IGA) team, thank you for your inquiry regarding compounding hydroxychloroquine or chloroquine.

We will make every effort to respond to your question in a timely manner, but due to the COVID-19 pandemic, we may be delayed in responding.

Best Regards,

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



**From:** Jennifer Zaelit <jzaelit@utah.gov>  
**Sent:** Friday, March 20, 2020 2:33 PM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** Hydroxychloroquine / chloroquine shortage

Would you be able to help me determine who I should speak to regarding compounding hydroxychloroquine or chloroquine?

With some pharmacies in the State of Utah finding the product on backorder. We have had several calls asking if they could compound the drug. Has any guidance been released yet?

Thanks in advance for your help.

Sincerely,

--

Jennifer Zaelit  
Bureau Manager  
Division of Occupational and Professional Licensing  
160 East 300 South  
Salt Lake City, Utah 84114-6741  
801-530-6628  
[www.dopl.utah.gov](http://www.dopl.utah.gov)

This email is provided for general informational purposes and it is not intended to provide legal advice or to substitute for the advice of an attorney. If you have specific legal questions, read the relevant law or consult your attorney. Any information provided in this email is not intended to be a final decision binding upon the Division because laws and procedures are subject to change and the Division may not have all relevant information necessary to provide a complete or accurate response. You will be notified in a separate written correspondence when official action is taken by the Division.

---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/24/2020 8:39:24 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Hydroxychloroquine / chloroquine shortage

See below

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** IGA <IGA@fda.hhs.gov>  
**Sent:** Friday, March 20, 2020 2:48 PM  
**To:** Jennifer Zaelit <jzaelit@utah.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Hydroxychloroquine / chloroquine shortage

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Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



**From:** Jennifer Zaelit <jzaelit@utah.gov>  
**Sent:** Friday, March 20, 2020 2:33 PM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** Hydroxychloroquine / chloroquine shortage

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With some pharmacies in the State of Utah finding the product on backorder. We have had several calls asking if they could compound the drug. Has any guidance been released yet?



Thanks in advance for your help.

Sincerely,

--

Jennifer Zaelit  
Bureau Manager  
Division of Occupational and Professional Licensing  
160 East 300 South  
Salt Lake City, Utah 84114-6741  
801-530-6628  
[www.dopl.utah.gov](http://www.dopl.utah.gov)

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 3/24/2020 9:10:44 AM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** RE: FDA Policy Update Re: COVID-19 Test Development and Distribution

(b)(5)

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 9:10 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: FDA Policy Update Re: COVID-19 Test Development and Distribution

She's jumping in! (b)(5)

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 9:09 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: FDA Policy Update Re: COVID-19 Test Development and Distribution

(b)(5)

This

is confusing.

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 9:07 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: FDA Policy Update Re: COVID-19 Test Development and Distribution

FYI.

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

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

**Sent:** Tuesday, March 24, 2020 7:54 AM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; (b)(6) <(b)(6)>

(b)(6) @fda.hhs.gov

**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; CDRH-EUA-Templates <(b)(6)@fda.hhs.gov>

**Subject:** RE: FDA Policy Update Re: COVID-19 Test Development and Distribution

Hi Karen,

CDRH is part of the supply chain group copied here, so can weigh in if needed. For these types of inquiries, CDRH would best be able to triage the question about flexibilities for tests (whether international or domestic). The question below seems to be focused on whether certain international tests that might be donated to CA could be used. I've copied the CDRH email box for awareness, or Ken can: "Contact our toll-free phone line 24 hours a day: 1-888-INFO-FDA (1-888-463-6332), then press star (\*)."

Thanks,  
Brooke

Brooke Courtney, JD, MPH  
Senior Regulatory Counsel  
COVID-19 (Operations--Supply Chain)  
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:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Sent:** Tuesday, March 24, 2020 12:50 AM

**To:** 2019-nCoV FDA IMG Operations Supply Chain <2019-nCoV-FDA-IMG-Operations-Supply-Chain@fda.hhs.gov>

**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>

**Subject:** Fwd: FDA Policy Update Re: COVID-19 Test Development and Distribution

Don't know if you've seen this yet. I think you're the right place to send this (b)(5)

(b)(5) Please advise. Thank you!!

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) will return call on work cell  
Email: Karen.meister@fda.hhs.gov

---

**From:** Johnston, Ken - PH <(b)(6)>

**Date:** March 23, 2020 at 8:08:31 PM EDT

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>, Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>, CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>

**Subject:** RE: FDA Policy Update Re: COVID-19 Test Development and Distribution

Good evening,

Just wondering if you have any clarification on my question below regarding international test kit manufacturers. I have local sources that may be willing to donate kits.

Thank you,  
-Ken

---

**From:** Johnston, Ken - PH  
**Sent:** Friday, March 20, 2020 2:40 PM  
**To:** 'Meister, Karen G' <Karen.Meister@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; 'Sauer, Robert' <Robert.A.Sauer@fda.hhs.gov>; CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>  
**Subject:** RE: FDA Policy Update Re: COVID-19 Test Development and Distribution

Thank you, Karen, for your reply and helpful FAQs. Also thanks to Robert Sauer who provided the attached reply. However, there is a bit of a conflict in your responses. Robert indicated that the policy does apply to international manufacturers. Please clarify.

---

**From:** Meister, Karen G [mailto:Karen.Meister@fda.hhs.gov]  
**Sent:** Friday, March 20, 2020 1:58 PM  
**To:** Johnston, Ken - PH <Ken.Johnston@dph.sbcounty.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: FDA Policy Update Re: COVID-19 Test Development and Distribution

The following information does not seem to mention internationally developed tests. We are trying to get more information on that. In the meantime, however, the following link may be helpful if you haven't already seen it.

FDA's hotline (1-888-INFO-FDA) is available 24 hours a day for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples. We also encourage labs to reach out at [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov) with any questions related to diagnostic development. Also, see frequently asked questions: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/fags-diagnostic-testing-sars-cov-2>.

Thank you for reaching out. Please don't hesitate to reach out to me at any of the numbers below. Stay safe.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office*

*(b)(6) (work cell)  
(b)(6) (personal cell- I will call you back on work phone)*

---

**From:** Johnston, Ken - PH <Ken.Johnston@dph.sbcounty.gov>  
**Sent:** Friday, March 20, 2020 3:06 PM  
**To:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
**Subject:** FDA Policy Update Re: COVID-19 Test Development and Distribution

Hello Ms. Caccamo,

I have a question about the updated FDA policy on March 16 regarding distribution of new commercially-developed COVID-19 tests and the recommendations for developing serological tests prior to the FDA granting an EUA.

Does this apply to tests that are developed internationally? Or do you have additional guidance for internationally developed tests?

I have attached an example for your reference. Thank you in advance for any guidance you can provide.

**Ken Johnston**  
Quality and Compliance Officer  
**Department of Public Health**  
Phone: 909-387-6304  
351 N. Mt. View Avenue  
San Bernardino CA 92415



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---

**Sent:** 3/24/2020 1:50:41 PM  
**To:** Gras, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=896294988ddc451f93b1073f119943af-Ruth.Gras]  
**Subject:** RE: Executive Orders

(b)(6)

---

**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 1:47 PM  
**To:** IGA Staff <IGASStaff@fda.hhs.gov>  
**Subject:** FW: Executive Orders

Forwarding to IGA colleagues. I must have received this in response to the blood supply email from last week.

---

**From:** Governor of South Dakota <GovernorNoem@state.sd.us>  
**Sent:** Tuesday, March 24, 2020 10:36 AM  
**To:** Governor of South Dakota <GovernorNoem@state.sd.us>  
**Subject:** Executive Orders

Good Morning,

Using the science, data, and facts that we have at our disposal, I issued Executive Orders 2020-07 and 2020-08 yesterday to provide guidelines related to COVID-19 to businesses, healthcare providers, and community leaders. As you know, thousands of people in South Dakota depend on public health guidance as well as a functioning economy.

If you should have questions, please reach out to our office at 605-773-3212 or call 1-800-997-2880. We are also updating covid.sd.gov on a daily basis.

Sincerely,

Governor Noem

---

**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 3/24/2020 3:16:07 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Request for Input for 24 March Update on FDA 2019-nCoV SITREP

Great – thank you!

---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 3:16 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Request for Input for 24 March Update on FDA 2019-nCoV SITREP

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Thanks!

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 3:09 PM  
**To:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>  
**Cc:** Price, William <William.Price@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Lockheed, Matthew <Matthew.Lockheed@fda.hhs.gov>  
**Subject:** RE: Request for Input for 24 March Update on FDA 2019-nCoV SITREP

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- Senate HELP Majority staff briefing on hand sanitizer guidance
- Phone call between Rep. Cleaver & Dr. Anand Shah
- House E&C Bipartisan staff briefing on Remdesivir

**Upcoming meetings:** None

**Legislative inquiries:**

- OL: Rep. DesJarlais inquiry re manufacturing essential medical supplies
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- OL: Rep. Katko inquiry re hydroxychloroquine
- OL: Rep. Colin Peterson inquiry re ventilator shortage solution
- OL: Rep. Hudson inquiry re COVID Positive Test Protocols
- OL: Rep. Bera inquiry re COVID-19 Serology testing
- OL: Sen. Booker inquiry re masks
- OL: Oversight inquiry re hand sanitizer
- OCA: Rep. Aderholt inquiry re hospital masks
- IGA: Oregon state inquiry re masks

Thanks!

Caitlin

---

**From:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>

**Sent:** Tuesday, March 24, 2020 10:09 AM

**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Gindes, Melinda F <Melinda.Gindes@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Newkirk, Ryan <Ryan.Newkirk@fda.hhs.gov>

**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>

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Best,  
Greg

**Gregory Measer, JD**

*Regulatory Counsel*

Office of Counterterrorism and Emerging Threats  
Office of the Chief Scientist, Office of the Commissioner  
U.S. Food and Drug Administration  
202-774-4146 / [Gregory.Measer@fda.hhs.gov](mailto:Gregory.Measer@fda.hhs.gov)



---

**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 3/24/2020 3:17:41 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
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Thanks.

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Thanks!

Caitlin

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**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Gindes, Melinda F <Melinda.Gindes@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Newkirk, Ryan <Ryan.Newkirk@fda.hhs.gov>

**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>

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U.S. Food and Drug Administration  
202-774-4146 / [Gregory.Measer@fda.hhs.gov](mailto:Gregory.Measer@fda.hhs.gov)



---

**Sent:** 3/24/2020 3:37:43 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]  
**Subject:** FW: [EXTERNAL] Question

Good afternoon,

IGA received the request below requesting “any guidance on using anesthesia equipment, in place of a ventilator in response to COVID-19”.

---

**From:** Ramos, Maribel <MRamos@nga.org>  
**Sent:** Tuesday, March 24, 2020 3:20 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** Question

Hello all,

I hope you all are doing ok. I am writing to ask if FDA has sent out any guidance on using anesthesia equipment, in place of a ventilator in response to COVID-19?

Thanks for any help!

Maribel

The information contained in this electronic transmission, including any attachments, is for the exclusive use of the intended recipient(s) and may contain information that is privileged, proprietary, and/or confidential. If the reader of this transmission is not an intended recipient, or a person responsible for delivering it to the intended recipient, you are hereby notified that any review, dissemination, distribution, or copying of this communication is strictly prohibited. If you have received this communication in error, please immediately notify the sender and delete this message.

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---

**Sent:** 3/24/2020 5:07:04 PM  
**To:** Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**CC:** Pennington, Caitlin [Caitlin.Pennington@fda.hhs.gov]  
**Subject:** RE: Question

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 24, 2020 at 4:56:53 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Question

Thanks Erica- Did you copy Caitlin so she can track? Thanks!

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 4:52 PM  
**To:** MRamos@nga.org  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Question

Good afternoon Maribel,

Thank you for your email requesting “any guidance on using anesthesia equipment, in place of a ventilator in response to COVID-19”. FDA plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic and is committed to providing timely guidance to support response efforts to this pandemic. FDA has issued the following guidance titled **Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency** to provide a policy to help expand the availability of ventilators as well as other respiratory devices and their accessories during this pandemic. This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act. FDA’s guidance on ventilators can be found at: <https://www.fda.gov/media/136318/download>.

For specific questions, manufacturers should send an email to [CDRH-COVID19-Ventilators@fda.hhs.gov](mailto:CDRH-COVID19-Ventilators@fda.hhs.gov). We hope this information is helpful.

For general FDA-related inquiries, please feel free to contact FDA’s IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

Erica.White@fda.hhs.gov

-----



---

**From:** Ramos, Maribel <MRamos@nga.org>

**Sent:** Tuesday, March 24, 2020 3:20 PM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>;  
Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>

**Subject:** Question

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 3/24/2020 5:11:05 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Re: Oregon Inquiry re: PPE

Thanks.

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 24, 2020 at 4:57:54 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: Oregon Inquiry re: PPE  
**Importance:** High

FYI- On the call with OL, Lauren referred me to this info that she just got today. I need to forward to Caitlin.

---

**From:** Meister, Karen G  
**Sent:** Tuesday, March 24, 2020 4:55 PM  
**To:** (b)(6) MCCOLAUGH Annie GOV <Annie.MCCOLAUGH@oregon.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; (b)(6)@oregon.gov  
**Subject:** Oregon Inquiry re: PPE  
**Importance:** High

Hi Zach and Annie-

Nick Alexander asked us to follow-up with you. This is the very latest information we can share.

FDA has guidance on PPE forthcoming but in the meantime, you can share the below with companies re: masks and gowns:

**Gowns:**

Surgical gowns (including surgical isolation gowns), surgical hoods, and surgical togas are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material. FDA regulates surgical gowns, surgical isolation gowns, surgical hoods and surgical togas as Class II devices and assesses them for liquid barrier protection among other things.



FDA does not object to your marketing and distribution of the gown and surgical apparel products in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

**Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let us know if you have any questions.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA*

U.S. Food and Drug Administration  
(301) 796-8916.office

(b)(6) (work cell)  
(b)(6) (personal cell- I will call you back on work phone)

---

**From:** Swint, Zachariah D. EOP/WHO (b)(6)  
**Sent:** Tuesday, March 24, 2020 4:22 PM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** FW: Urgent need

Nick,

Any help on this OR question? Can you point me in the right direction?

Zach

---

**From:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Sent:** Tuesday, March 24, 2020 4:20 PM  
**To:** Swint, Zachariah D. EOP/WHO (b)(6)  
**Cc:** MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>  
**Subject:** Urgent need

Zach – Thanks for the check-in a few minutes ago. We have an urgent need I'm hoping you can clear up later today: We have a number of companies in Oregon, from (b)(4) on down, who want to manufacture various PPE for us and can do so quickly. We are out of gowns at the state, for example.

My colleague, Annie McColaugh, contacted both the FDA and the National Institute for Occupational Health and Safety to get specifications for various PPE items, but they were unwilling to provide specs for masks that would conform with FDA approval and limit liability on the manufacturer. They have a pattern on the web site, but that's not the same thing – we need the specs for mass manufacturing that will allow our manufacturers to make this stuff without liability.

Can you please help?

Thanks -- Nik

Nik Blosser  
Chief of Staff  
Oregon Governor Kate Brown  
503-373-1565

Assistant: (b)(6)  
(b)(6)@oregon.gov

---

**From:** BLOSSER Nik \* GOV [Nik.BLOSSER@oregon.gov]  
**Sent:** 3/24/2020 5:56:04 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Swint, Zachariah D. EOP/WHO (b)(6); MCCOLAUGH Annie \* GOV [Annie.MCCOLAUGH@oregon.gov]  
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**Subject:** Re: Oregon Inquiry re: PPE

Hi, Karen – Understood. My Governor wants to place a call to Sec Azar or the Vice President about this, and I'm trying to find out if that's needed. We have manufacturers ready to make this stuff, and I'm trying to understand why the specs aren't something that can just be approved for manufacture with liability protection. Are they really that complicated? Can you help me understand why there would be a delay in just approving specs for other manufacturers to make this stuff without liability?

Thanks -- Nik

Nik Blosser  
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Oregon Governor Kate Brown  
503-373-1565

Assistant: (b)(6)  
(b)(6)@oregon.gov

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**From:** "Meister, Karen G" <Karen.Meister@fda.hhs.gov>  
**Date:** Tuesday, March 24, 2020 at 2:39 PM  
**To:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>, "Swint, Zachariah D. EOP/WHO" (b)(6); Annie McColaugh <Annie.MCCOLAUGH@oregon.gov>  
**Cc:** "White, Erica" <Erica.White@fda.hhs.gov>, "Alexander, Nicholas" <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

Hi Nik-

I don't have answers about the liability questions. Regarding the timing of a guidance, I don't know when one will issue but FDA is getting things out daily to respond to the coronavirus outbreak. And as soon as one issues, we will forward it.

Thank you for your patience and persistence. I am reachable at any of the numbers below at any time.

Karen

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**From:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Sent:** Tuesday, March 24, 2020 5:12 PM  
**To:** Swint, Zachariah D. EOP/WHO (b)(6); MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>

**Subject:** Re: Oregon Inquiry re: PPE

Karen –

Okay, just so I understand: the way I read this, we can have manufacturers go ahead and make it but they won't be protected from liability, is that correct?

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Is different FDA guidance imminent, and if so what is the timeframe?

Thanks -- Nik

Nik Blosser  
Chief of Staff  
Oregon Governor Kate Brown  
503-373-1565

Assistant: (b)(6)  
(b)(6)@oregon.gov

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**From:** "Swint, Zachariah D. EOP/WHO" <(b)(6)>  
**Date:** Tuesday, March 24, 2020 at 1:57 PM  
**To:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Subject:** FW: Oregon Inquiry re: PPE

FYI, still tracking down swab question.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 4:55 PM  
**To:** Swint, Zachariah D. EOP/WHO <(b)(6)> MCCOLAUGH Annie GOV <Annie.MCCOLAUGH@oregon.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; (b)(6)@oregon.gov  
**Subject:** Oregon Inquiry re: PPE  
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Hi Zach and Annie-

Nick Alexander asked us to follow-up with you. This is the very latest information we can share.

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**Gowns:**

Surgical gowns (including surgical isolation gowns), surgical hoods, and surgical togas are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material. FDA regulates surgical gowns, surgical isolation gowns, surgical hoods and surgical togas as Class II devices and assesses them for liquid barrier protection among other things.

FDA does not object to your marketing and distribution of the gown and surgical apparel products in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

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- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
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- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

**Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

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- 1) It states it may be used when FDA cleared masks are unavailable;
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- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

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Please let us know if you have any questions.

Karen

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
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(301) 796-8916 office

(b)(6) work cell)  
personal cell- I will call you back on work phone)

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**From:** Swint, Zachariah D. EOP/WHO (b)(6)  
**Sent:** Tuesday, March 24, 2020 4:22 PM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** FW: Urgent need

Nick,

Any help on this OR question? Can you point me in the right direction?

Zach

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**To:** Swint, Zachariah D. EOP/WHO (b)(6)  
**Cc:** MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>  
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Assistant: (b)(6)  
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**Sent:** 3/24/2020 8:16:30 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6756008a41407282a58324a7b5144a-OCCRequests]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; 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]  
**Subject:** Re: Oregon Inquiry re: PPE and liability with uncleared FDA products

(b)(5)

(b)(5) I think they will be reaching out HHS IGA on this so FDA folks may not need to do anything further at this point.

Thanks so much, Karen and team.

— Nick

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 24, 2020 at 8:05:53 PM EDT  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
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(b)(5)

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**Sent:** Tuesday, March 24, 2020 5:39 PM

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(b)(6)

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**Sent:** 3/24/2020 10:23:49 PM  
**To:** OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc756008a41407282a58324a7b5144a-OCCRequests]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; 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]  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

Thanks so much (b)(5) please let us know.

---

**From:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Date:** March 24, 2020 at 8:25:48 PM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>, OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

Thanks Karen. I've forwarded Nick's email to the SMEs for awareness.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 8:23 PM  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
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**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

Thank you. I don't know (b)(5) Thank you. Karen

---

**From:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 8:21 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

I'm not familiar with the declaration but I'm reaching out to SMEs here (b)(5) (b)(5)

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Sent:** Tuesday, March 24, 2020 8:20 PM

**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

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**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

(b)(5)

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**From:** Meister, Karen G

**Sent:** Tuesday, March 24, 2020 8:06 PM

**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>

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(b)(5)

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**Date:** Tuesday, March 24, 2020 at 1:57 PM  
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Zach

---

**From:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>

**Sent:** Tuesday, March 24, 2020 4:20 PM

**To:** Swint, Zachariah D. EOP/WHO (b)(6)

**Cc:** MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>

**Subject:** Urgent need

Zach – Thanks for the check-in a few minutes ago. We have an urgent need I'm hoping you can clear up later today: We have a number of companies in Oregon, from (b)(4) on down, who want to manufacture various PPE for us and can do so quickly. We are out of gowns at the state, for example.

My colleague, Annie McColaugh, contacted both the FDA and the National Institute for Occupational Health and Safety to get specifications for various PPE items, but they were unwilling to provide specs for masks that would conform with FDA approval and limit liability on the manufacturer. They have a pattern on the web site, but that's not the same thing – we need the specs for mass manufacturing that will allow our manufacturers to make this stuff without liability.

Can you please help?

Thanks -- Nik



Nik Blosser  
Chief of Staff  
Oregon Governor Kate Brown  
503-373-1565

Assistant:

(b)(6)

(b)(6)

@oregon.gov

---

**Sent:** 3/25/2020 7:48:33 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Coronavirus (COVID-19) Update: Daily Roundup

Personall

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 10:43 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup

EYL: OL sends this Daily Roundup

(b)(5)

(b)(5)

We'll talk.

---

**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 9:07 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup

The FDA Office of Legislation would like to bring to your attention update on the following actions taken today by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA is facilitating access to convalescent plasma, antibody-rich blood products that are taken from blood donated by people who have recovered from the COVID-19 virus, that could shorten the length, or lessen the severity, of the illness. The agency will be using multiple pathways to support these efforts and has posted information for investigators wishing to study convalescent plasma for use in patients with serious or immediately life-threatening COVID-19 infections through the process of single patient emergency Investigational New Drug Applications for individual patients. The FDA also is actively engaging with researchers to discuss the possibility of collaboration on the development of a master protocol for the use of convalescent plasma, with the goal of reducing duplicative efforts.
- In response to this evolving public health emergency and continued filtering facepiece respirator (FFR or respirator) shortages, FDA has concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized respirators listed in Exhibit 1 are authorized for use in healthcare settings by healthcare personnel (HCP) when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.
  - Letter of Authorization
  - Non-NIOSH Approved Respirator EUA FAQ

- The FDA issued a Consumer Update advising consumers to be beware of fraudulent coronavirus tests, vaccines and treatments. The FDA is particularly concerned that deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm. It's likely that the products do not do what they claim, and the ingredients in them could cause adverse effects and could interact with, and potentially interfere with, essential medications. There are no FDA-approved products to prevent COVID-19. For example, the FDA is aware of people trying to prevent COVID-19 by taking a product called chloroquine phosphate, which is sold to treat parasites in aquarium fish. Products for veterinary use or for "research use only" may have adverse effects, including serious illness and death, when taken by people. The agency warns not to take any form of chloroquine unless it has been prescribed by a health care provider and obtained from legitimate sources.
- Diagnostics update: In certain emergencies, the FDA can often quickly issue an emergency use authorization for diagnostic tests based on FDA's rolling review of data and where the request meets certain criteria. In the COVID-19 pandemic, the FDA has worked with more than 190 test developers who have said they will be submitting applications to make tests that detect the virus. To date, 16 emergency use authorizations have been issued for nation-wide use, including one today. Under our laboratory developed test policy during COVID-19, the FDA has been notified by more than 65 laboratories.
- The FDA issued a Letter to Industry that includes steps the Center for Devices and Radiological Health (CDRH) has taken to prioritize work that advances the nation's response during the Coronavirus Disease 2019 (COVID-19) public health emergency. These steps seek to address the impact of COVID-19 public health emergency on day-to-day operations in CDRH and in the medical device industry, while ensuring that government and private sector efforts to respond to this national emergency receive the highest priority.
- The FDA provided flexibility to veterinarians who want to utilize telemedicine to prescribe certain drugs for animals by temporarily suspending enforcement of portions of the federal veterinarian-client-patient relationship requirements. This helps veterinarians continue to care for animals while minimizing person-to-person contact between veterinary staff and the animal owner or caretaker, allowing for the social distancing that is so important in limiting the further spread of coronavirus.
- The FDA explained how the agency is working with experts around the world to find ways to prevent and treat COVID-19, including collaborating with international organizations to facilitate the development of a vaccine: FDA Voices: FDA and EMA Collaborate to Facilitate SARS-CoV-2 Vaccine Development.
- The FDA took action to increase U.S. supplies to support the U.S. response to COVID-19 by providing instructions to manufacturers importing personal protective equipment and other devices. The agency is engaging with importers and others involved in the import trade community during this pandemic to facilitate the entry of needed products, including PPE, into the U.S. These instructions to importers clarify the types of PPE that can be imported without engaging with FDA. They also include information about the type of information importers can submit to facilitate their entries.
- The FDA provided an update, FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19, to explain that the U.S. food supply remains safe for both people and animals. There is no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19. Additionally, overall, retail supply chains remain strong, and the FDA is working with food manufacturers and grocery stores to closely monitor the human food supply chain for any shortages. The same is true for animal food. The FDA is monitoring the availability of foods for livestock and pets. There are no shortages, and no current disruptions in the pet and livestock food supply chain.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** Alexander, Nicholas [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=08E1FD211C4A4C96BE426218BD0711E9-NICHOLAS.AL]  
**Sent:** 3/25/2020 9:27:01 AM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.BI]  
**Subject:** RE: Oregon Inquiry re: PPE

This was a sep inquiry from hand sanitizers related to the mfg of masks and the liability protections associated with such production.

FWIW.

Hope e wry one is doing ok.

— Nick

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Date:** March 25, 2020 at 9:05:34 AM EDT  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>, Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>, Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

Got it – we’ve added this to our doc of all things hand sanitizers. Thanks!!

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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 8:02 AM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

Morning- to add my 2 cents.... I did share yesterday’s PPE with Annie in Oregon Gov’s office AND Erica called her. I think the question that Nick sent is a follow up question from another OR Gov’s office staffer re: liability. Hope this clarifies things a bit. (or not!)

Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA

U.S. Food and Drug Administration  
Office: (240) 338-7449  
Christopher.Campbell@fda.hhs.gov



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**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 6:45 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

(b)(5)



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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 6:42 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

They keep asking. 😞

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**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 6:23 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

I thought y'all said this one was closed out? Happy to run an answer down but just wanted to double check first. Thanks!

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 24, 2020 at 5:35:03 PM EDT  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>, Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE

Can you check with JIC and see what we can say about liability as raised below? Thanks.

---

**From:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Sent:** Tuesday, March 24, 2020 5:12 PM  
**To:** Swint, Zachariah D. EOP/WHO <Zachariah.Swint@oregon.gov> (b)(6) MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** Re: Oregon Inquiry re: PPE

Karen –

Okay, just so I understand: the way I read this, we can have manufacturers go ahead and make it but they won't be protected from liability, is that correct?

When you say "FDA does not object" what does that mean legally for a company who wants to help but doesn't want to put themselves in legal jeopardy?

Is different FDA guidance imminent, and if so what is the timeframe?

Thanks -- Nik

Nik Blosser  
Chief of Staff  
Oregon Governor Kate Brown  
503-373-1565

Assistant: (b)(6)  
(b)(6)@oregon.gov

---

**From:** "Swint, Zachariah D. EOP/WHO" <Zachariah.D.Swint2@who.eop.gov>  
**Date:** Tuesday, March 24, 2020 at 1:57 PM  
**To:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Subject:** FW: Oregon Inquiry re: PPE

FYI, still tracking down swab question.

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 4:55 PM  
**To:** Swint, Zachariah D. EOP/WHO (b)(6) MCCOLAUGH Annie GOV  
<Annie.MCCOLAUGH@oregon.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>;  
(b)(6)@oregon.gov  
**Subject:** Oregon Inquiry re: PPE  
**Importance:** High

Hi Zach and Annie-

Nick Alexander asked us to follow-up with you. This is the very latest information we can share.

FDA has guidance on PPE forthcoming but in the meantime, you can share the below with companies re: masks and gowns:

**Gowns:**

Surgical gowns (including surgical isolation gowns), surgical hoods, and surgical togas are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material. FDA regulates surgical gowns, surgical isolation gowns, surgical hoods and surgical togas as Class II devices and assesses them for liquid barrier protection among other things.

FDA does not object to your marketing and distribution of the gown and surgical apparel products in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

### **Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let us know if you have any questions.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration*

(301) 796-8916 office

(b)(6)

(work cell)

(personal cell- I will call you back on work phone)

---

**From:** Swint, Zachariah D. EOP/WHO <Zachariah.D.Swint2@who.eop.gov>

**Sent:** Tuesday, March 24, 2020 4:22 PM

**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>

**Subject:** FW: Urgent need

Nick,

Any help on this OR question? Can you point me in the right direction?

Zach

---

**From:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>

**Sent:** Tuesday, March 24, 2020 4:20 PM

**To:** Swint, Zachariah D. EOP/WHO; (b)(6)

**Cc:** MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>

**Subject:** Urgent need

Zach – Thanks for the check-in a few minutes ago. We have an urgent need I'm hoping you can clear up later today: We have a number of companies in Oregon, from (b)(4) on down, who want to manufacture various PPE for us and can do so quickly. We are out of gowns at the state, for example.

My colleague, Annie McColaugh, contacted both the FDA and the National Institute for Occupational Health and Safety to get specifications for various PPE items, but they were unwilling to provide specs for masks that would conform with FDA approval and limit liability on the manufacturer. They have a pattern on the web site, but that's not the same thing – we need the specs for mass manufacturing that will allow our manufacturers to make this stuff without liability.

Can you please help?

Thanks -- Nik

Nik Blosser

Chief of Staff

Oregon Governor Kate Brown

503-373-1565

Assistant; (b)(6)

(b)(6)

@oregon.gov



---

**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/25/2020 2:00:20 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Letter from Governor Brown to VP Pence and Sec. Azar on PPE  
**Attachments:** 03.25.20\_OR Governor Brown Letter to VP Pence HHS Azar on DPA and PPE.pdf

**Importance:** High

Man, she hit everybody up on this one!

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Christopher.Campbell@fda.hhs.gov



---

**From:** MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>

**Sent:** Wednesday, March 25, 2020 1:56 PM

**To:** Pottebaum, Nic D. EOP/WHO <(b)(6)> Obenshain, Tucker T. EOP/OVP  
(b)(6) Swint, Zachariah D. EOP/WHO (b)(6) Johnston,  
Darcie (OS) <Darcie.Johnston@hhs.gov>; Stevens, Lee R (OS) <Lee.Stevens@hhs.gov>; Meister, Karen G  
<Karen.Meister@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Alexander, Nicholas  
<Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; robby.wehagen@fema.dhs.gov;  
Kimberly.helm@fema.dhs.gov

**Subject:** Letter from Governor Brown to VP Pence and Sec. Azar on PPE

**Importance:** High

All,

Please find attached an urgent request from Governor Brown to Vice President Pence and Secretary Azar to use the powers of the DPA to direct industries to manufacture PPE items and ventilators; and for FDA and CDC to provide guidance and specs for additional manufacturers, like those in Oregon, to help make PPE or work with them to expedite the approval process to do that. We are facing a PPE crisis in Oregon that need immediate action.

Let me know if you have any questions. Appreciate your attention to this.

Best,  
Annie

**Annie McColaugh**

Director, Washington DC Office  
Oregon Governor Kate Brown

P: (202) 508-3847 | C: (b)(6)

444 N Capitol St NW, Ste 134; Washington, DC 20001

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 3/26/2020 8:10:09 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 25, 2020

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 9:42 PM  
**To:** IGA Staff <IGASTaff@fda.hhs.gov>; Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 25, 2020

Chris/Erica-

Could one of you please outreach this first thing in the AM? I will look for a time to have a team meeting tomorrow. I hope we can all get on the OL call tomorrow AM.

Hope you all had a good evening! Karen

---

**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 9:28 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 25, 2020

The FDA Office of Legislation would like to bring to your attention update on the following actions taken today by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- In response to the demand for alcohol-based hand sanitizers and their active ingredient, alcohol, certain entities that are not currently regulated by the FDA as drug manufacturers have requested guidance on the preparation and distribution of alcohol for incorporation into hand sanitizer products for the public's use. The FDA issued another guidance for industry about hand sanitizers, [Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) Guidance for Industry](#). The guidance is for firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the active pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency.
- The FDA added hydroxychloroquine sulfate to category 1 under the [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act](#). The FDA does not intend to object to registered outsourcing facilities using hydroxychloroquine (or chloroquine phosphate, which was already on category 1), to compound human drugs provided the drugs meet other conditions and requirements in the FD&C Act. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The FDA is placing hydroxychloroquine sulfate on category 1

after it reviewed the nomination and determined there was sufficient information for the agency to evaluate the substance for outsourcing facilities to use in compounding. When FDA categorized hydroxychloroquine sulfate it did not change its approach, but we prioritized this substance due to the COVID-19 pandemic. There are currently no FDA approved therapeutics or drugs to treat, cure or prevent COVID-19; however, there are FDA-approved treatments that may help ease the symptoms of COVID-19. Additionally, state-licensed pharmacies and federal facilities that compound drugs under section 503A of the FD&C Act may compound drugs using hydroxychloroquine sulfate or chloroquine phosphate bulk drug substances because they are components of an FDA-approved drug, provide other requirements in the Act are met.

- The FDA issued an emergency use authorization for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA. If you have questions, please email [CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov).
- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 190 test developers who have said they will be submitting applications to make tests that detect the virus. To date, 1 emergency use authorizations have been issued for nation-wide use. Additionally, under our COVID-19 laboratory developed test policy, the FDA has been notified by more than 100 laboratories. The FDA also added additional updates to its COVID-19 Diagnostics FAQ.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/26/2020 8:13:58 AM  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 25, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention update on the following actions taken today by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- In response to the demand for alcohol-based hand sanitizers and their active ingredient, alcohol, certain entities that are not currently regulated by the FDA as drug manufacturers have requested guidance on the preparation and distribution of alcohol for incorporation into hand sanitizer products for the public's use. The FDA issued another guidance for industry about hand sanitizers, [Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) Guidance for Industry](#). The guidance is for firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the active pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency.
- The FDA added hydroxychloroquine sulfate to category 1 under the [Interim Policy on Compounding Using Bulk Drug Substances Under Section 503B of the Federal Food, Drug, and Cosmetic Act](#). The FDA does not intend to object to registered outsourcing facilities using hydroxychloroquine (or chloroquine phosphate, which was already on category 1), to compound human drugs provided the drugs meet other conditions and requirements in the FD&C Act. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. The FDA is placing hydroxychloroquine sulfate on category 1 after it reviewed the nomination and determined there was sufficient information for the agency to evaluate the substance for outsourcing facilities to use in compounding. When FDA categorized hydroxychloroquine sulfate it did not change its approach, but we prioritized this substance due to the COVID-19 pandemic. There are currently no FDA approved therapeutics or drugs to treat, cure or prevent COVID-19; however, there are FDA-approved treatments that may help ease the symptoms of COVID-19. Additionally, state-licensed pharmacies and federal facilities that compound drugs under section 503A of the FD&C Act may compound drugs using hydroxychloroquine sulfate or chloroquine phosphate bulk drug substances because they are components of an FDA-approved drug, provide other requirements in the Act are met.
- The FDA issued an [emergency use authorization](#) for ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories. Manufacturers and other stakeholders may submit a request to FDA under the process outlined in the EUA to have their device(s) added to the EUA. If you have questions, please email [CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov).
- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 190 test developers who have said they will be submitting applications to make tests that detect the virus. To date, 1 emergency use authorizations have been issued for nation-wide use. Additionally, under our [COVID-19 laboratory developed test policy](#), the FDA has been notified by more than 100 laboratories. The FDA also added additional updates to its [COVID-19 Diagnostics FAQ](#).

#### Additional Resources:

- [Coronavirus Disease 2019 \(COVID-19\)](#)

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/26/2020 8:22:53 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; adearinger@ky.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylyntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 25, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention update on the following actions taken today by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- In response to the demand for alcohol-based hand sanitizers and their active ingredient, alcohol, certain entities that are not currently regulated by the FDA as drug manufacturers have requested guidance on the preparation and distribution of alcohol for incorporation into hand sanitizer products for the public's use. The FDA issued another guidance for industry about hand sanitizers, [Temporary Policy for Manufacture of Alcohol for Incorporation Into Alcohol-Based Hand Sanitizer Products During the Public Health Emergency \(COVID-19\) Guidance for Industry](#). The guidance is for firms that manufacture alcohol (i.e., ethanol or ethyl alcohol) for use as the active pharmaceutical ingredient (API) in alcohol-based hand sanitizers for consumer use and for use as health care personnel hand rubs for the duration of the public health emergency.
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**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**Sent:** 3/26/2020 2:33:45 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

Hello,

Question for you,

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 8:23 PM  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

Thank you. I don't know.

(b)(5)

(b)(5)

You have enough other stuff to do. Thank you. Karen

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**From:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 8:21 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

I'm not familiar with the declaration but I'm reaching out to SMEs here

(b)(5)

(b)(5)

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 8:20 PM  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** RE: Oregon Inquiry re: PPE and liability with uncleared FDA products

(b)(5)

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**From:** Meister, Karen G  
**Sent:** Tuesday, March 24, 2020 8:06 PM  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** FW: Oregon Inquiry re: PPE and liability with uncleared FDA products

Hi OCC-

Sorry to bother you now. WH is calling because they're concerned

(b)(5)

(b)(5)

Nike has offered to make PPE but has asked the governor's office for information re: their liability if the products aren't FDA cleared. As you may know FDA has granted companies latitude in the current situation per the email below. We would like to know how to answer the following questions:

### Questions

1. "Okay, just so I understand: the way I read this, we can have manufacturers go ahead and make it but they won't be protected from liability, is that correct?" (b)(5)

(b)(5)

2. When you say "FDA does not object" what does that mean legally for a company who wants to help but doesn't want to put themselves in legal jeopardy? (b)(5)

(b)(5)

**From:** Meister, Karen G

**Sent:** Tuesday, March 24, 2020 5:39 PM

**To:** BLOSSER, Nik \* GOV <Nik.BLOSSER@oregon.gov>; Swint, Zachariah D. EOP/WHO

(b)(6)

@who.eop.gov>; MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>

**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>

**Subject:** RE: Oregon Inquiry re: PPE

Hi Nik-

I don't have answers about the liability questions. Regarding the timing of a guidance, I don't know when one will issue but FDA is getting things out daily to respond to the coronavirus outbreak. And as soon as one issues, we will forward it.

Thank you for your patience and persistence. I am reachable at any of the numbers below at any time.

Karen

---

**From:** BLOSSER, Nik \* GOV <Nik.BLOSSER@oregon.gov>

**Sent:** Tuesday, March 24, 2020 5:12 PM

**To:** Swint, Zachariah D. EOP/WHO (b)(6) @who.eop.gov>; MCCOLAUGH Annie \* GOV

<Annie.MCCOLAUGH@oregon.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>

**Subject:** Re: Oregon Inquiry re: PPE

Karen –

Okay, just so I understand: the way I read this, we can have manufacturers go ahead and make it but they won't be protected from liability, is that correct?

When you say "FDA does not object" what does that mean legally for a company who wants to help but doesn't want to put themselves in legal jeopardy?



Is different FDA guidance imminent, and if so what is the timeframe?

Thanks -- Nik

Nik Blosser  
Chief of Staff  
Oregon Governor Kate Brown  
503-373-1565

Assistant: Jen Andrew  
jennifer.j.andrew@oregon.gov

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**From:** "Swint, Zachariah D. EOP/WHO" (b)(6)@who.eop.gov  
**Date:** Tuesday, March 24, 2020 at 1:57 PM  
**To:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Subject:** FW: Oregon Inquiry re: PPE

FYI, still tracking down swab question.

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 4:55 PM  
**To:** Swint, Zachariah D. EOP/WHO (b)(6)@who.eop.gov; MCCOLAUGH Annie GOV <Annie.MCCOLAUGH@oregon.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; jennifer.i.andrew@oregon.gov  
**Subject:** Oregon Inquiry re: PPE  
**Importance:** High

Hi Zach and Annie-

Nick Alexander asked us to follow-up with you. This is the very latest information we can share.

FDA has guidance on PPE forthcoming but in the meantime, you can share the below with companies re: masks and gowns:

**Gowns:**

Surgical gowns (including surgical isolation gowns), surgical hoods, and surgical togas are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material. FDA regulates surgical gowns, surgical isolation gowns, surgical hoods and surgical togas as Class II devices and assesses them for liquid barrier protection among other things.

FDA does not object to your marketing and distribution of the gown and surgical apparel products in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable

- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

**Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let us know if you have any questions.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916.office*

**(b)(6)** *(work cell)  
(personal cell- I will call you back on work phone)*

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**From:** Swint, Zachariah D. EOP/WHO (b)(6)@who.eop.gov>  
**Sent:** Tuesday, March 24, 2020 4:22 PM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** FW: Urgent need

Nick,

Any help on this OR question? Can you point me in the right direction?

Zach

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**From:** BLOSSER Nik \* GOV <Nik.BLOSSER@oregon.gov>  
**Sent:** Tuesday, March 24, 2020 4:20 PM  
**To:** Swint, Zachariah D. EOP/WHO (b)(6)@who.eop.gov>  
**Cc:** MCCOLAUGH Annie \* GOV <Annie.MCCOLAUGH@oregon.gov>  
**Subject:** Urgent need

Zach – Thanks for the check-in a few minutes ago. We have an urgent need I'm hoping you can clear up later today: We have a number of companies in Oregon, from (b)(4) down, who want to manufacture various PPE for us and can do so quickly. We are out of gowns at the state, for example.

My colleague, Annie McColaugh, contacted both the FDA and the National Institute for Occupational Health and Safety to get specifications for various PPE items, but they were unwilling to provide specs for masks that would conform with FDA approval and limit liability on the manufacturer. They have a pattern on the web site, but that's not the same thing – we need the specs for mass manufacturing that will allow our manufacturers to make this stuff without liability.

Can you please help?

Thanks -- Nik

Nik Blosser  
Chief of Staff  
Oregon Governor Kate Brown  
503-373-1565

Assistant: Jen Andrew  
jennifer.j.andrew@oregon.gov

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/26/2020 4:49:32 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**CC:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** FW: Guidance on the use of Chloroquine and Hydroxychloroquine  
**Attachments:** Guidance on Dispensing Prescriptions for Chloroquine and Hydroxychloroquine in Response to COVID-19.pdf

Here you go Chris.

E

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**From:** Joe Dodge <j.dodge@pharmacy.nv.gov>  
**Sent:** Thursday, March 26, 2020 4:46 PM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** Fw: Guidance on the use of Chloroquine and Hydroxychloroquine

Mr. Elwood asked me to forward the email below to this address. Please respond as soon as possible.

Thank you

Joe Dodge

---

**From:** Joe Dodge  
**Sent:** Monday, March 23, 2020 11:15:02 AM  
**To:** Elwood, Will  
**Subject:** Guidance on the use of Chloroquine and Hydroxychloroquine

Hi Will,

I have attached documentation that we sent to all pharmacies in Nevada. We wanted to make sure that the information related to the FDA was consistent with the messaging from the FDA. Do you know who may be able to take a look at the document and provide feedback?

Thanks,

Joe Dodge, Pharm D  
Inspector

Nevada State Board of Pharmacy  
1050 E. Flamingo Ste E217  
Las Vegas, NV, 89119

Office: 702.486.6420 Ext 157  
Fax: 702.486.7903  
E-mail: [j.dodge@pharmacy.nv.gov](mailto:j.dodge@pharmacy.nv.gov)  
Web Page: [www.bop.nv.gov](http://www.bop.nv.gov)

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/26/2020 9:06:32 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

fyi

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**From:** Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 8:44 PM  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Cc:** Hunt, Christine <Christine.Hunt@fda.hhs.gov>; Madni, Rubina <Rubina.Madni@fda.hhs.gov>  
**Subject:** RE: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Good evening,  
OCC clears the press release on coronavirus treatment acceleration program/plasma.  
Kind regards,  
Denise Zavagno

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**From:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 5:56 PM  
**To:** Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>; Madni, Rubina <Rubina.Madni@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Subject:** FW: FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

For 8:30 PM review, on convalescent plasma and treatment acceleration program. If you'd like me to ask for more time or a drugs counselor, too, let me know.

Best,  
Christine

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**From:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 5:43 PM  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Subject:** FOR JIC REVIEW: Press Release on Coronavirus Treatment Acceleration Program/Plasma

Hi all,

Attached for JIC review by **8:30 PM TODAY** is a draft press release regarding the Coronavirus Treatment Acceleration Program and our work on convalescent plasma/hyperimmune globulin. This press release is based on the previously cleared press release on convalescent plasma/hyperimmune globulin, CBER-cleared talkers on new developments on this topic and CDER/CBER-cleared talking points on the Coronavirus Treatment Acceleration Program.

Please make edits in SharePoint: <http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/DRAFT PR CTAP%20+%20Plasma%2003262020.docx>

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



**(b)(5)**

**(b)(5)**

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**Sent:** 3/27/2020 7:31:31 AM  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

The FDA Intergovernmental Affairs Team would like to bring to your attention updates on the following actions taken today by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA issued guidance today on a [Temporary Policy Regarding Nutrition Labeling of Certain Packaged Food During the COVID-19 Public Health Emergency](#). The FDA is issuing this guidance to provide restaurants and food manufacturers with flexibility regarding nutrition labeling so that they can sell certain packaged foods during the COVID-19 pandemic. For example, restaurants may have purchased ingredients that they can no longer use to prepare restaurant food and instead wish to sell to their customers.
- The FDA posted [questions and answers related to consumer use of hand sanitizer during the COVID-19 public health emergency](#). The FDA wants to make consumers aware of the steps the agency is taking to increase the supply of hand sanitizer during this public health emergency. The questions also discuss hand washing, expiration dates and other frequently asked questions by consumers on hand sanitizer.
- Late yesterday, the FDA issued an immediately in effect guidance: [Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease-2019 \(COVID-19\) Public Health Emergency](#). The FDA believes the policy set forth in this guidance may help address urgent public health concerns by helping to expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals.
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- **Diagnostics update to date:** During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 17 emergency use authorizations have been issued for diagnostic tests, including the AvellinoCoV2 test, which is a real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Additionally, FDA has been notified that more than 100 laboratories have begun testing under the policies set forth in our [COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance](#). The FDA also continues to keep its [COVID-19 Diagnostics FAQ](#) up to date.

#### **Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)



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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/27/2020 7:34:20 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; adearinger@ky.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylyntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

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**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**Sent:** 3/27/2020 8:23:15 AM  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Personal protective equipment question

Good morning Mr. Marriott,

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**From:** IGA  
**Sent:** Thursday, March 26, 2020 3:34 PM  
**To:** Marriott, Rodrick <Rodrick.Marriott@ct.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Personal protective equipment question

Good afternoon Mr. Marriott,

Thank you for your email below regarding the manufacturing of garbing/PPE and whether FDA has relaxed registration requirements or enforcement. FDA has guidance on PPE forthcoming but in the meantime, I would like to share the information below re: masks and gowns:

**Gowns:**

Surgical gowns (including surgical isolation gowns), surgical hoods, and surgical togas are intended to be worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, bodily fluids, and particulate material. FDA regulates surgical gowns, surgical isolation gowns, surgical hoods and surgical togas as Class II devices and assesses them for liquid barrier protection among other things.

FDA does not object to your marketing and distribution of the gown and surgical apparel products in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

**Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let us know if you have any questions.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



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**From:** Marriott, Rodrick <Rodrick.Marriott@ct.gov>

**Sent:** Tuesday, March 24, 2020 6:17 AM

**To:** IGA <IGA@fda.hhs.gov>

**Subject:** Personal protective equipment question

IGA Team,

My name is Rod Marriott and I am the Director of Drug Control in Connecticut. Can you help me identify requirements for the manufacture of garbing/PPE? Has FDA issues any relaxing of registration or enforcement? Anything you can provide will be helpful.

Thanks,  
Rod

Rodrick J. Marriott, PharmD

Director

**Department of Consumer Protection - Drug Control Division**

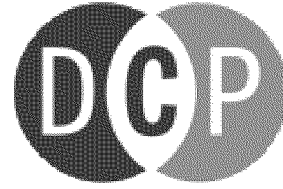
450 Columbus Blvd, 901, Hartford, CT 06103

Office 860-713-6079 | Fax 860-706-1277

For contact information or scheduling – [click here](#)

Chrissy Ely, Secretary II

Phone 860-713-6089 | Fax 860-706-1365



[www.ct.gov/dcp/dcd](http://www.ct.gov/dcp/dcd)

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**From:** Campbell, Christopher [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8E72B376D4A54DD08FC0F7AE915401D4-CHRISTOPHER]  
**Sent:** 3/27/2020 8:27:28 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

Ok, got it.

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Christopher.Campbell@fda.hhs.gov



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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, March 27, 2020 8:26 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

Yeap. 7:34am. It's in the IGA box.

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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Friday, March 27, 2020 8:25 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

Hi- Did you send this out this morning? I didn't get anything from you or the IGA box. Thanks, Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Christopher.Campbell@fda.hhs.gov



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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 10:04 PM  
**To:** IGA Staff <IGASStaff@fda.hhs.gov>; IGA <IGA@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

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**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 10:02 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 26, 2020

The FDA Office of Legislation would like to bring to your attention update on the following actions taken today by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information. Thank yo

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2 in nasopharyngeal and oropharyngeal swab specimens collected from individuals suspected of COVID-19 by their healthcare provider. Additionally, FDA has been notified that more than 100 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)



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**Sent:** 3/27/2020 11:39:45 AM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; adearinger@kentucky.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharell@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; Jillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; Meister, Karen G  
[mailto:Erica.White@fda.hhs.gov] [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; jblumenstock@astho.org; cmullen@astho.org; IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]; acasalotti@naccho.org  
**Subject:** FDA takes action to help increase U.S. supply of ventilators and respirators for protection of health care workers, patients

Good morning,

FDA's Intergovernmental Affairs (IGA) team would like to bring to your attention an announcement regarding FDA's latest action to help increase the supply of ventilators, ventilator tubing connectors, and ventilator accessories, as well as filtering facepiece respirators (FFRs) due to shortages during COVID-19, as part of our commitment to ease burdens on the health care system during this pandemic.

The FDA issued an Emergency Use Authorization (EUA) to allow for the emergency use in health care settings of certain ventilators, anesthesia gas machines modified for use as ventilators, and positive pressure breathing devices modified for use as ventilators (collectively referred to as "ventilators"), ventilator tubing connectors, and ventilator accessories that the FDA determines meet specified criteria for safety, performance and labeling.

Ventilator tubing connectors are used for multiplexing certain continuous ventilators intended for use in a health care facility, which means one ventilator may be used for multiple patients simultaneously. The devices that are eligible for inclusion under this EUA are those that are not currently marketed in the U.S., or that are currently marketed in the U.S. but a modification is made to the device that would trigger the requirement that a manufacturer submit a new premarket notification (510(k)) to the FDA, as discussed in the agency's Ventilator Enforcement Policy.

This EUA demonstrates our ability to react and adapt quickly during this pandemic by providing maximum regulatory flexibility and helping to increase the U.S. ventilator inventory so that very ill patients have access to lifesaving devices they need, while still providing appropriate FDA oversight.

The FDA also issued an EUA for certain imported non-NIOSH-approved respirators that have been designed, evaluated and validated to meet a performance standard specified in the EUA and/or that have a marketing authorization in certain specified jurisdictions, subject to the conditions of authorization. Respirators that are authorized under the EUA

are authorized for use in health care settings by health care personnel in accordance with recommendations from the Centers for Disease Control and Prevention to prevent exposure to airborne particulates.

This new EUA covering certain respirators does not affect the previous March 2, 2020 EUA, which authorizes, in part, the emergency use of certain respirators approved by NIOSH, for use in health care settings by health care providers.

For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#). This EUA does not permit use of authorized respirators by the general public.

We hope this information is helpful.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 3/27/2020 11:51:44 AM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; adearinger@kentucky.gov; alexander.billieux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharell@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; kalanikaneko@gmail.com; emais.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; jblumenstock@astho.org; cmullen@astho.org; IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]; acasalotti@naccho.org  
**Subject:** FDA takes action to help increase U.S. supply of ventilators and respirators for protection of health care workers, patients

Good morning,

FDA's Intergovernmental Affairs (IGA) team would like to bring to your attention an announcement regarding FDA's latest action to help increase the supply of ventilators, ventilator tubing connectors, and ventilator accessories, as well as filtering facepiece respirators (FFRs) due to shortages during COVID-19, as part of our commitment to ease burdens on the health care system during this pandemic.

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Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/29/2020 12:13:14 PM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** Re: Lack of COVID testing in Imperial Valley

Thanks Jen.

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Date:** March 29, 2020 at 9:20:09 AM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Lack of COVID testing in Imperial Valley

Hi Karen – this looks like a state Senator from California, if you can reach out.

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: 240-328-7224  
jennifer.tomasello@fda.hhs.gov



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

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**From:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>  
**Sent:** Saturday, March 28, 2020 8:57 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>  
**Subject:** FW: Lack of COVID testing in Imperial Valley

JT, can you take this one?  
Thanks,  
Toby

**Toby Lowe**  
CDRH/OIR  
Tel: 301-796-6512

*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>*

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**From:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>  
**Sent:** Saturday, March 28, 2020 8:48 PM  
**To:** Lowe, Toby A <Toby.Lowe@fda.hhs.gov>  
**Subject:** FW: Lack of COVID testing in Imperial Valley

Want to respond? Or should I file?  
Yvonne

---

**From:** Brian Tyson { (b)(6) }  
**Sent:** Saturday, March 28, 2020 7:51 PM  
**To:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>  
**Subject:** Lack of COVID testing in Imperial Valley

Please see attached letter and help is get testing kits!!

Sent from my iPhone

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/29/2020 3:57:08 PM  
**To:** (b)(6)  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Lack of COVID testing in Imperial Valley  
**Attachments:** COVID testing letter senator.docx

Hi Brian-

We suggest reaching out to the EUA approved manufacturers directly to purchase kits- <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

What specific type of kit can you run on your platform? We think that most manufacturers except Roche and Cepheid have product on shelves. We can get contact information for manufacturers if you need it.

Also, your regional FEMA may be able to help:

*"If you are a hospital or healthcare provider in need of medical supplies, please contact your state, local, tribal or territory department of public health and/or emergency management agency. Any needs that cannot be met by the state or tribe are then sent to the respective FEMA regional office who are coordinating requirements through the FEMA National Response Coordination Center. FEMA is working with HHS and other federal agencies to fulfill requests and ship supplies as quickly as possible."*

<https://www.fema.gov/news-release/2020/03/27/fema-offers-ways-private-sector-help-fight-covid-19>;

<https://www.fema.gov/disaster/4482>

Good luck. My contact information is below. Thank you for all you are doing for your patients and community.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office*

**(b)(6)** (work cell)  
personal cell- I will call you back on work phone)

---

**From:** Brian Tyson (b)(6)  
**Sent:** Saturday, March 28, 2020 7:51 PM  
**To:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>  
**Subject:** Lack of COVID testing in Imperial Valley

Please see attached letter and help is get testing kits!!

Sent from my iPhone

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**From:** Inniss, Blair [binniss@law.umaryland.edu]  
**Sent:** 3/29/2020 5:12:08 PM  
**To:** Hoke, Kathleen [khole@law.umaryland.edu]; Lowrey, Kerri [klowrey@law.umaryland.edu]; Swinburne, Mathew [mswinburne@law.umaryland.edu]; Inniss, Blair [binniss@law.umaryland.edu]; Griest, Megan [MGriest@law.umaryland.edu]  
**Subject:** Legal Resource Center for Public Health Policy - Legislative Update Call 3/30  
**Attachments:** Bi-Weekly Legislative Call Agenda 3.30.20.docx; Legal Resource Center Public Health Tracker - 2020 Legislative Session 3.29.20.pdf

Good afternoon,

Please find the Legal Resource Center's legislative tracking chart attached to this email. Our tracking document can also be viewed in real time [HERE](#). Our students have highlighted bills that passed (green) or failed (red) in committee and bills that are enrolled for the Governor's signature (yellow). Bills that officially become law are being added to the "Passed" tab.

You will also see a new tab, aptly named "COVID-19," that lists bills that have been introduced/passed in response to the COVID-19 pandemic. These are Maryland-specific bills.

Our next and final bi-weekly legislative update call will be on **MONDAY, March 30<sup>th</sup>** at 1:00 p.m. The agenda is attached.

Call-in Number: (712) 770-5505

Access Code: (b)(6)

The final legislative summary will be emailed out soon.

Thank you and stay safe!

Blair Inniss, J.D.  
Staff Attorney  
Legal Resource Center for Public Health Policy  
University of Maryland Carey School of Law  
500 W. Baltimore Street  
Baltimore, MD 21201  
Tel (410) 706-5999 Fax (410) 706-1129  
[binniss@law.umaryland.edu](mailto:binniss@law.umaryland.edu)



---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/30/2020 8:43:29 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirlev@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 27, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken Friday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration Friday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA is working closely with manufacturers to make sure that they continue to notify the agency of any permanent discontinuance or interruption of drug and biological product manufacturing in a timely manner. Today, the agency published [guidance](#) for immediate implementation about the importance of these notifications, the timelines for drug and biologic manufacturers to follow when notifying the FDA, and the details for manufacturers to provide about the discontinuance or interruption in manufacturing. Along with the requirements in the statute and implementing regulations, the guidance requests that applicants and manufacturers provide additional details and follow additional procedures to make sure the FDA has the specific information it needs to help prevent or mitigate shortages.
- The FDA issued a [Consumer Update, Food Safety and Availability During the Coronavirus Pandemic](#), to describe the many ways the agency is working to help ensure the foods you, your family, and your pets eat are safe and available.
- The FDA issued a [letter to stakeholders about the imminent threat to the health of consumers who may take chloroquine phosphate products used to treat disease in aquarium fish, thinking the products are interchangeable with FDA-approved drugs \(used to treat malaria and certain other conditions in humans\) that are being studied as a COVID-19 treatment for humans](#). Chloroquine products sold for aquarium use have not been evaluated by the FDA to determine whether they are safe, effective, properly manufactured, and adequately labeled for use in fish--let alone humans.
- **Diagnostics update to date:** During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 19 [emergency use authorizations](#) have been issued for diagnostic tests. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our [COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance](#). The FDA also continues to keep its [COVID-19 Diagnostics FAQ](#) up to date.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/30/2020 11:27:03 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus Update: FDA expedites review of diagnostic tests to combat COVID-19

Good morning,

The FDA Intergovernmental Affairs Team would like to bring your attention to the following [press release](#) on FDA's actions to expedite review of diagnostic tests to combat COVID-19.

This morning, FDA also issued an immediately in effect [guidance](#) to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this public health emergency.

If you have any questions, please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you.

## Coronavirus Update: FDA expedites review of diagnostic tests to combat COVID-19

*This statement is attributed to: FDA Commissioner Stephen M. Hahn, M.D.*

The U.S. Food and Drug Administration has been providing unprecedented flexibility to labs and manufacturers to develop and offer COVID-19 tests across the U.S. The FDA's regulations have not hindered or been a roadblock to the rollout of tests during this pandemic. Every action the FDA has taken during this public health emergency to address the COVID-19 pandemic has balanced the urgent need to make diagnostic tests available with providing a level of oversight that ensures accurate tests are being deployed. Moreover, as in previous emergencies, the FDA has been extremely proactive and supportive of test development by all comers—laboratories, and large and small commercial manufacturers—offering our expertise and support to speed development and to quickly authorize tests that the science supports.

It is not the FDA's role to develop tests or decide what tests a health care professional uses. Our role is to determine if the tests developed by others provide accurate and reliable results, even when some would prefer that we let tests on the market without evidence that they work. It's critical that the tests used work. False results can also contribute to the spread of COVID-19. We want our treatments to be tested for effectiveness and reviewed by the FDA. We want the same for our tests—assurances that they are accurate and effective.

### *Developing a test:*

- Typically, with an emerging health threat, the Centers for Disease Control and Prevention (CDC) is the first developer of a diagnostic test.
- Samples of the virus are crucial to confirming the accuracy of the test.
- CDC has first access to viral samples that other test developers do not. CDC also manufactures their own tests for distribution to their national network of public health labs. In this pandemic, CDC encountered problems manufacturing their test. FDA assisted CDC in their work to resolve the issue and utilize a commercial manufacturer to make tests for any laboratory, not only public health labs.
- Viral samples became commercially available to private sector test developers in later February, when the National Institutes of Health's partner BEI Resources began selling vials of the virus grown from material provided by CDC.
- Laboratories have always had the ability to develop their own tests in the U.S.; the COVID-19 outbreak did not change this. Once a developer has a viral sample, they can confirm the accuracy of their test very quickly, usually in two to three days.
- In the future, making viral samples available earlier to commercial developers will be crucial to deploying tests quickly. Moreover, CDC's test should be manufactured by a commercial entity with the requisite expertise.

### *Timeline of FDA support for test developers:*

- Since the beginning of January, the FDA has worked with more than 230 test developers who have or are expected to submit requests for FDA emergency authorization of their tests; to date, 20 authorizations have been granted.
- In addition, more than 110 laboratories have notified the FDA that they have begun using their own tests.
- For interested developers, the FDA provided recommendations for how to check a test for accuracy as well as a short form to make it easy to share their test information quickly in support of an Emergency Use Authorization (EUA).

### *Emergency Use Authorization authorities:*

- An EUA, put into place by Congress, is a relaxed standard that allows tests to be made available based on less data than in non-urgent circumstances and allows for expedited FDA review.
- EUA authority is not a barrier to test availability.
- For diagnostics, EUA still requires an accurate test, but allows the FDA to quickly review, in as little as a day, which it has done repeatedly.

### *FDA policy updates:*

- The FDA recognized the urgent need for even faster testing availability. Although laboratories could use the EUA pathway, many were hesitant or didn't know the pathway was available to them.

- To respond to this need, the FDA revised the process to allow labs to begin testing prior to FDA review of their validation data. This policy change was an unprecedented action to expand access to testing. Nevertheless, in the first week, only six laboratories took advantage of this further streamlined process because many laboratories did not have a test, or did not have the viral samples to check the accuracy of their test.
- In addition, the FDA implemented another change to empower states to take responsibility for tests developed and used by laboratories in their states without FDA review.

The FDA has and will continue to play a pivotal role in this emergency response. Our doors will continue to remain open.

Additional Resources:

- [Novel Coronavirus](#)

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**Sent:** 3/30/2020 12:05:54 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: PLEASE READ ASAP--verification of vendor requested

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Sunday, March 29, 2020 12:12 PM  
**To:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Re: PLEASE READ ASAP--verification of vendor requested

Thanks Kim!

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (b)(6)  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

---

**From:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Date:** March 29, 2020 at 11:27:01 AM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>, Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFAIMGPlanning@fda.hhs.gov>  
**Subject:** FW: PLEASE READ ASAP--verification of vendor requested

Good Morning,

Sharing a response to an RFI below from CDRH to NH state for IGA's awareness.

Thanks,  
Kim

Kim Garner  
LCDR, U.S. Public Health Service  
Interagency Information Liaison/RFI Lead  
2019 Novel Coronavirus (COVID-19) IMG  
U.S. Food and Drug Administration  
**Desk:** 240-402-6549  
**Cell:** (b)(6)  
**Email:** kimberly.garner@fda.hhs.gov  
**IMG Planning Section email:**  
2019-nCoVFAIMGPlanning@fda.hhs.gov

---

**From:** Harper, Jennifer <Jennifer.Harper@dos.nh.gov>  
**Sent:** Sunday, March 29, 2020 10:23 AM  
**To:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** Re: PLEASE READ ASAP--verification of vendor requested

Thank you I have forwarded this to our logistics unit.

Appreciate your ongoing assistance.

You mentioned yesterday you were rotating out Monday, is there someone else I can work with in your absence in the event we get further requests from Chinese companies?

Thanks-Jenn

Jennifer L. Harper, Director  
NH Homeland Security & Emergency Management  
(b)(6) Cell

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On: 29 March 2020 09:38,  
"Garner, Kimberly" <Kimberly.Garner@fda.hhs.gov> wrote:

**EXTERNAL:** Do not open attachments or click on links unless you recognize and trust the sender.

---

Good Morning Jen,

CDRH has reviewed the attached documents. Please see their response below:

- KN95s are the Chinese version of a N95. However they are not the same as N95s and the standards that are used for testing them are different. The KN95s are not authorized under our current EUA. However, while we cannot assure the performance of the KN95s, they are better than not having respirators. Please see CDC's guidance <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html>.
- The "medical masks" are acceptable if labeled as "face mask" under section V.C. of the guidance.
- The surgical masks should have fluid resistance testing under Section V.D. of the guidance or should be labeled as "face mask". However FDA premarket review is not needed.
- For the gowns, they require 510k clearance. It is unclear from the material provided if the gowns are 510(k) cleared.
- The test kit shown on the materials is not one that is authorized under an Emergency Use Authorization.
- Standalone face shields are Class I exempt. We would not be able to confirm if they register and list with us. These are likely ok to purchase.

Hopefully this is helpful. Let us know if there are additional questions.

Best,

Kim Garner  
LCDR, U.S. Public Health Service  
Interagency Information Liaison/RFI Lead  
2019 Novel Coronavirus (COVID-19) IMG  
U.S. Food and Drug Administration  
Desk: 240-402-6549

Cell: (b)(6)

Email: kimberly.garner@fda.hhs.gov

IMG Planning Section email:

2019-nCoVFDAIMGPlanning@fda.hhs.gov

---

**From:** Harper, Jennifer <Jennifer.Harper@dos.nh.gov>  
**Sent:** Sunday, March 29, 2020 8:18 AM  
**To:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: PLEASE READ ASAP--verification of vendor requested  
**Importance:** High

Good Morning Kim – Can you please provide me an update on this request from yesterday as soon as possible – my Governor is asking when (if) we can place orders for PPE.

Thank you -

Jenn

Jennifer L. Harper, Director  
NH Homeland Security and Emergency Management

Office (603) 223-3615

Cell: (b)(6)



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**From:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Sent:** Saturday, March 28, 2020 5:48 PM  
**To:** Harper, Jennifer <Jennifer.Harper@dos.nh.gov>  
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: PLEASE READ ASAP--verification of vendor requested

**EXTERNAL:** Do not open attachments or click on links unless you recognize and trust the sender.

Hi Jennifer,

Message received. I will follow-up with our Center for Devices and Radiological Health (CDRH) on your inquiry below. I see that this is time sensitive, so will try to get you a response as soon as possible.

Please also continue to copy the Planning distro that I've copied here. I will be rotating off of the FDA Incident Management Group (IMG) on Monday and want to make sure you're able to get a response from someone on the IMG if you have additional inquiries.

Thanks,  
Kim



Kim Garner  
LCDR, U.S. Public Health Service  
Interagency Information Liaison/RFI Lead  
2019 Novel Coronavirus (COVID-19) IMG  
U.S. Food and Drug Administration  
**Desk:** 240-402-6549  
**Cell:** (b)(6)  
**Email:** kimberly.garner@fda.hhs.gov  
**IMG Planning Section email:**  
2019-nCoVFDAIMGPlanning@fda.hhs.gov

---

**From:** Harper, Jennifer <Jennifer.Harper@dos.nh.gov>  
**Sent:** Saturday, March 28, 2020 5:34 PM  
**To:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Cc:** Harper, Jennifer <Jennifer.Harper@dos.nh.gov>  
**Subject:** PLEASE READ ASAP--verification of vendor requested  
**Importance:** High

Hi Kimberly – I was given your name by US DHS Intergovernmental Affairs as you assisted in verifying a Chinese company that NH wanted to purchase PPE from yesterday. We were not confident of the paperwork that they provided to us and with your assistance we were able to order it today so thank you!

I've attached 2 vendors that we need verified by FDA to ensure my Governor that the companies are in fact legitimate. We are looking to spend several million dollars for PPE and want FDA's assurance that its FDA approved before we order it – tomorrow.

Please call my cell if you have any questions.

Thank you for your prompt attention to this matter.

*Jenn*

**Jennifer L. Harper, Director**

NH Department of Safety  
Division of Homeland Security and Emergency Management  
110 Smokey Bear Boulevard (physical)  
33 Hazen Drive (mailing)  
Concord, NH 03305

Office: (603) 223-3615  
Cell: (b)(6)

**ReadyNH.gov**  
TAKE ACTION. BE SAFE.

---

**Sent:** 3/30/2020 12:13:05 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FW: For OCC Review by 9AM on Tues, Mar 24: responses to device shortages inquiries

Hi Caitlin,

Are the finalized versions of this

---

**From:** Price, William <William.Price@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 2:35 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>  
**Subject:** RE: For OCC Review by 9AM on Tues, Mar 24: responses to device shortages inquiries

Thank you for flagging this, Caitlin! This is very helpful. Also adding Mike and Michelle.

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 2:34 PM  
**To:** Price, William <William.Price@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** FW: For OCC Review by 9AM on Tues, Mar 24: responses to device shortages inquiries

FYI - We're good to use these responses for our inquiries. These are responses companies would get if they contacted the device shortage inbox instead of their member of Congress but we are fine to use going forward. So, maybe pick the appropriate response and also add in a sentence at the end on "If the company decides to move forward and would like to sell product to the USG, please reach out to FEMA at this website \*insert website\*"

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 10:33 AM  
**To:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** RE: For OCC Review by 9AM on Tues, Mar 24: responses to device shortages inquiries

We're good to use these. These are responses companies would get if they contacted the device shortage inbox instead of their member of Congress but we are fine to use going forward. So, maybe pick the appropriate response and also add in a sentence at the end on "If the company decides to move forward and would like to sell product to the USG, please reach out to FEMA at this website \*insert website\*"

---

**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 10:27 AM  
**To:** Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** FW: For OCC Review by 9AM on Tues, Mar 24: responses to device shortages inquiries

I'm checking on whether we can use these responses for our inquiries because they are perfect.

---

**From:** MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>

**Sent:** Monday, March 23, 2020 10:32 PM

**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

**Cc:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

**Subject:** For OCC Review by 9AM on Tues, Mar 24: responses to device shortages inquiries

Hi,

Can OCC please review these responses to device shortages inquiries **by 9AM on Tues, Mar 24**? These are CDRH cleared. Sending as JIC/IMG FYI due to expedited review request.

CDRH is requesting expedited clearance to provide timely response to the large number of inquiries coming in regarding device shortages.

Responses pasted below for quick reference:

### **Device Shortage Inquiry Responses**

There are seven responses to address the following inquiries:

- Individual citizens looking to make own devices
- Individual or hospital reporting a shortage – All others – Not PPE or N95
- PPE And N95 Combined – For Individuals Experiencing Local Shortage
- Manufacturers inquiring about marketing ventilators and accessories in the US
- Manufacturers inquiring about marketing GOWNS in the US
- Manufacturers inquiring about marketing MASKS in the US
- Manufacturers inquiring about marketing products in the US other than Masks, gowns, or ventilators

#### **Individual citizens looking to make own devices**

**(b)(5)**

**(b)(5)**

**(b)(5)**

**(b)(5)**

**(b)(5)**

**(b)(5)**



**(b)(5)**

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  
240-402-0962 (Office)

(b)(6)

lori.maclennan@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:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/30/2020 9:01:51 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gomez]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 30, 2020

---

**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 6:03 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 30, 2020

The FDA Office of Legislation would like to bring to your attention update on the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information.  
Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- On March 28, 2020, the FDA issued an Emergency Use Authorization (EUA) to allow hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions. The SNS, managed by ASPR, will work with the Federal Emergency Management Agency (FEMA) to ship donated doses to states.
- On March 29, 2020, the FDA issued an immediately in effect guidance that outlines an enforcement policy to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers. The devices include those intended to make devices sterile, kill pathogens or other microorganisms and kill pathogens or microorganisms in the air. This policy reflects FDA's commitment to ease burdens on health care providers and facilities as they face COVID-19.
- The FDA amended the Emergency Use Authorization (EUA) for the Battelle Decontamination System for use in decontaminating compatible N95 respirators for reuse by health care personnel during the COVID-19 pandemic. This EUA is an important step forward in helping to reduce shortages in critical N95 respirators, by allowing for these important devices, when decontaminated, to be reused by medical professionals on the front lines of the COVID-19 pandemic.

- On March 30, 2020, the FDA issued an immediately in effect guidance to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this public health emergency.
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- The FDA issued an updated guidance, "Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic," with an appendix adding questions and answers on this subject. We plan to update this appendix as new questions arise. This guidance is intended for industry, investigators and institutional review boards and was issued because we recognize that the COVID-19 pandemic may impact the conduct of clinical trials of medical products, including drugs, devices and biological products.
- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 230 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 20 emergency use authorizations have been issued for diagnostic tests, including Abbott Diagnostics Scarborough, Inc., ID NOW COVID-19, a rapid (13 minutes or less) test. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 3/31/2020 8:27:23 AM  
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**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; kalanikaneko@gmail.com; emais.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 30, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken yesterday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- On March 28, 2020, the FDA issued an Emergency Use Authorization (EUA) to allow hydroxychloroquine sulfate and chloroquine phosphate products donated to the Strategic National Stockpile (SNS) to be distributed and used for certain hospitalized patients with COVID-19. These drugs will be distributed from the SNS to states for doctors to prescribe to adolescent and adult patients hospitalized with COVID-19, as appropriate, when a clinical trial is not available or feasible. The EUA requires that fact sheets that provide important information about using chloroquine phosphate and hydroxychloroquine sulfate in treating COVID-19 be made available to health care providers and patients, including the known risks and drug interactions. The SNS, managed by ASPR, will work with the Federal Emergency Management Agency (FEMA) to ship donated doses to states.
- On March 29, 2020, the FDA issued an immediately in effect guidance that outlines an enforcement policy to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers. The devices include those intended to make devices sterile, kill pathogens or other microorganisms and kill pathogens or microorganisms in the air. This policy reflects FDA's commitment to ease burdens on health care providers and facilities as they face COVID-19.
- The FDA amended the Emergency Use Authorization (EUA) for the Battelle Decontamination System for use in decontaminating compatible N95 respirators for reuse by health care personnel during the COVID-19 pandemic. This EUA is an important step forward in helping to reduce shortages in critical N95 respirators, by allowing for these important devices, when decontaminated, to be reused by medical professionals on the front lines of the COVID-19 pandemic.
- On March 30, 2020, the FDA issued an immediately in effect guidance to help expand the availability of surgical apparel for health care professionals, including gowns (togas), hoods, and surgeon's and patient examination gloves during this public health emergency.
- FDA and FTC issued warning letters to two companies for selling unapproved products claiming to mitigate, prevent, treat, diagnose or cure COVID-19. One of the companies, Corona-cure.com, was warned for selling the product Coronavirus Infection Prevention Nasal Spray with misleading claims on its website that its product is safe and/or effective for the treatment or prevention of COVID-19. The agencies also warned Carahealth for selling its herbal products, including "Carahealth Immune," with misleading claims of prevention and/or treatment of COVID-19. We are particularly concerned that unapproved drugs that claim to cure, treat, or prevent serious conditions may cause consumers to delay or stop appropriate medical treatment, leading to serious or life-threatening harm. There is currently no approved treatment or preventative measure for COVID-19. FDA and FTC are closely monitoring social media, the online marketplace, and incoming reports for fraudulent COVID-19 products on the market.
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- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 230 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 20 emergency use authorizations have been issued for diagnostic tests, including Abbott Diagnostics Scarborough, Inc., ID NOW COVID-19, a rapid (13 minutes or less) test. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

### **Additional Resources:**

Coronavirus Disease 2019 (COVID-19)

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/31/2020 7:32:39 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** FW: Personal Protection Equipment

FYI

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**From:** Meister, Karen G  
**Sent:** Tuesday, March 31, 2020 7:32 PM  
**To:** valerie.lott@dhhs.nc.gov  
**Subject:** Personal Protection Equipment

Hi Valerie-

Thanks for talking with me. As we discussed, following is some information on personal protection equipment:

Please see the following FDA website regarding emergency use authorizations for medical devices issued in connection with the corona virus: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>.

Last week, FDA issued guidance on Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings.

On March 30, FDA issued guidance on Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of gowns, other apparel, and gloves and helping to expand the availability of surgical apparel for health care professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency.

FDA does not object to marketing and distribution of gown and surgical apparel products in the healthcare setting without prior FDA 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;

8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

**Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let me know if you have additional questions. We know this is a difficult time.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office  
(240) 494-6228 mobile*

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**From:** Lott, Valerie <[valerie.lott@dhhs.nc.gov](mailto:valerie.lott@dhhs.nc.gov)>  
**Sent:** Tuesday, March 31, 2020 3:31 PM  
**To:** Deviceshortages <[Deviceshortages@fda.hhs.gov](mailto:Deviceshortages@fda.hhs.gov)>  
**Subject:** KN95

Hello,

Our state has purchased KN95s from a vendor after referencing the CDC's website "Strategies for Optimizing PPE...". Some of the vendors are being stopped at customs because the KN95s are not FDA approved devices. Please advise.



Valerie Lott, MPH, REHS  
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North Carolina Preparedness and Response  
225 N. McDowell St.  
1902 MSC  
Raleigh, NC 27699-1900  
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**888-820-0520 (PHP&R 24/7 On-call)**  
Valerie.Lott@dhhs.nc.gov



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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 3/31/2020 11:40:52 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gomez]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for March 31, 2020

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**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 10:17 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 31, 2020

The FDA Office of Legislation would like to bring to your attention update on the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information.  
Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- Today, the FDA stood up a new program to expedite the development of potentially safe and effective life-saving treatments. The program, known as the Coronavirus Treatment Acceleration Program (CTAP), is using every tool at the agency's disposal to bring new therapies to sick patients as quickly as possible, while at the same time supporting research to further evaluate whether these medical countermeasures are safe and effective for treating patients infected with this novel virus.
- Today, the FDA posted information regarding shortages of hydroxychloroquine and chloroquine to its drug shortages webpage, due to a significant surge in demand. The agency is working with manufacturers to assess their supplies and is actively evaluating market demand for patients dependent on hydroxychloroquine and chloroquine for treatment of malaria, lupus and rheumatoid arthritis. All manufacturers are ramping up production, and the agency's webpage displays current availability. The FDA is working with manufacturers to ensure this can happen expeditiously and safely. The U.S. Department of Health and Human Services (HHS) has also accepted 30 million doses of hydroxychloroquine sulfate to the national stockpile and one million doses of chloroquine phosphate for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials. Use of the donated medications is expected to help ease supply pressures for the drugs. This is a fluctuating and dynamic situation and the FDA is actively engaged. The agency is updating its shortages lists regularly and continuing to communicate in real-time so that patients and healthcare providers have the most current information on product shortages in the U.S.
- Today, the FDA and FTC issued warning letters to three companies for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure COVID-19. One of the companies warned, Halosense Inc., sells salt therapy

products with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19. Another company warned, Bioactive C60/FullerLifeC60 LLC, sells an unapproved and unauthorized product, "FullerLifeC60," with misleading claims that it can build up immunity to help treat or prevent COVID-19 in people. The third company warned, JRB Enterprise Group Inc. DBA Anti-Aging Bed, offers colloidal silver products for sale in the U.S. with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19. With these warning letters, the FDA is exercising its authority to protect consumers from companies selling unapproved products and making false or misleading claims during the COVID-19 pandemic.

- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. On March 30, FDA issued two additional emergency use authorizations for COVID-19 diagnostics, for a total of 22 authorized tests. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/1/2020 7:12:31 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for March 31, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken yesterday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

The U.S. Food and Drug Administration announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- Yesterday, the FDA stood up a new program to expedite the development of potentially safe and effective life-saving treatments. The program, known as the Coronavirus Treatment Acceleration Program (CTAP), is using every tool

at the agency's disposal to bring new therapies to sick patients as quickly as possible, while at the same time supporting research to further evaluate whether these medical countermeasures are safe and effective for treating patients infected with this novel virus.

- Yesterday, the FDA posted information regarding shortages of hydroxychloroquine and chloroquine to its drug shortages webpage due to a significant surge in demand. The agency is working with manufacturers to assess their supplies and is actively evaluating market demand for patients dependent on hydroxychloroquine and chloroquine for treatment of malaria, lupus and rheumatoid arthritis. All manufacturers are ramping up production, and the agency's webpage displays current availability. The FDA is working with manufacturers to ensure this can happen expeditiously and safely. The U.S. Department of Health and Human Services (HHS) has also accepted 30 million doses of hydroxychloroquine sulfate to the national stockpile and one million doses of chloroquine phosphate for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials. Use of the donated medications is expected to help ease supply pressures for the drugs. This is a fluctuating and dynamic situation and the FDA is actively engaged. The agency is updating its shortages lists regularly and continuing to communicate in real-time so that patients and healthcare providers have the most current information on product shortages in the U.S.
- Yesterday, the FDA and FTC issued warning letters to three companies for selling fraudulent products with claims to prevent, treat, mitigate, diagnose or cure COVID-19. One of the companies warned, Halosense Inc., sells salt therapy products with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19. Another company warned, Bioactive C60/FullerLifeC60 LLC, sells an unapproved and unauthorized product, "FullerLifeC60," with misleading claims that it can build up immunity to help treat or prevent COVID-19 in people. The third company warned, JRB Enterprise Group Inc. DBA Anti Aging Bed, offers colloidal silver products for sale in the U.S. with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19. With these warning letters, the FDA is exercising its authority to protect consumers from companies selling unapproved products and making false or misleading claims during the COVID-19 pandemic.
- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. On March 30, FDA issued two additional emergency use authorizations for COVID-19 diagnostics, for a total of 22 authorized tests. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

#### **Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/1/2020 9:49:16 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: KN95

I agree.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 9:42 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: KN95

Okay. If he replies, we will follow the same format. I am hesitant to send anything via email now b/c we simply don't know his specific questions.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 9:38 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: KN95

Erica-

Turns out I told her over the phone we couldn't say anything about the K95 masks and then sent this:

Thanks for talking with me. As we discussed, following is some information on personal protection equipment:

Please see the following FDA website regarding emergency use authorizations for medical devices issued in connection with the corona virus: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>.

Last week, FDA issued guidance on Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings.

On March 30, FDA issued guidance on Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of gowns, other apparel, and gloves and helping to expand the availability of surgical apparel for health care professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency.

FDA does not object to marketing and distribution of gown and surgical apparel products in the healthcare setting without prior FDA 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

#### **Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let me know if you have additional questions. We know this is a difficult time.

Karen

---

**From:** White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>  
**Sent:** Wednesday, April 01, 2020 7:31 AM  
**To:** Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>  
**Subject:** RE: KN95

Good morning,

Do you mind forwarding me your response to the KN95 mask questions. I would like to forward them to the Dr. that asked about them.

Thanks,  
E

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 8:52 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: KN95

Did this one.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 4:52 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: KN95

Hi! Here is another one – from the state of NC.

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



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

---

**From:** Deviceshortages <Deviceshortages@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 4:26 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Subject:** FW: KN95

**Jessica Cades, Ph.D.**  
*Project Manager*

CSPS | OPEQ | CDRH  
WO66-1536  
Jessica.Cades@fda.hhs.gov | (240) 402-3900

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**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Sent:** Tuesday, March 31, 2020 3:31 PM  
**To:** Deviceshortages <Deviceshortages@fda.hhs.gov>  
**Subject:** KN95

Hello,

Our state has purchased KN95s from a vendor after referencing the CDC's website "Strategies for Optimizing PPE...". Some of the vendors are being stopped at customs because the KN95s are not FDA approved devices. Please advise.

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health, Epidemiology Section  
North Carolina Preparedness and Response  
225 N. McDowell St.  
1902 MSC  
Raleigh, NC 27699-1900  
919-546-1823-office  
(b)(6) cell  
919-715-2246-fax  
**888-820-0520 (PHP&R 24/7 On-call)**  
Valerie.Lott@dhhs.nc.gov



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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 4/1/2020 9:57:11 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: KN95

(b)(5)

(b)(5)

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 9:50 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: KN95

(b)(5)

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**Sent:** Wednesday, April 01, 2020 9:42 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
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**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



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**Sent:** Tuesday, March 31, 2020 4:26 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Subject:** FW: KN95

**Jessica Cades, Ph.D.**

*Project Manager*

CSPS | OPEQ | CDRH

WO66-1536

Jessica.Cades@fda.hhs.gov | (240) 402-3900

*Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: [Survey Link](#)*

---

**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>

**Sent:** Tuesday, March 31, 2020 3:31 PM

**To:** Deviceshortages <Deviceshortages@fda.hhs.gov>

**Subject:** KN95

Hello,

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Valerie Lott, MPH, REHS

Industrial Hygiene Consultant Supervisor

Division of Public Health, Epidemiology Section

North Carolina Preparedness and Response

225 N. McDowell St.

1902 MSC

Raleigh, NC 27699-1900

919-546-1823-office

(b)(6) cell

919-715-2246-fax

**888-820-0520 (PHP&R 24/7 On-call)**

Valerie.Lott@dhhs.nc.gov



---

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**Sent:** 4/1/2020 11:40:33 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: [External] (b)(4), SC Manufacturing Company Information

Would send this through Jennifer Tomasello- the inquiry itself because it's a new subject.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 11:12 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Karen,

Let me know if this is okay.

(b)(4) (b)(5)

(b)(4) (b)(5)

---

**From:** White, Erica

**Sent:** Tuesday, March 31, 2020 9:28 AM

**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>

**Subject:** FW: [External (b)(4)] SC Manufacturing Company Information

Good morning everyone,

The question below is about (b)(4) I have the CDRH website regarding (b)(4) but I haven't seen anything related to them and COVID. I was wondering if there was any language out there already, or if this needs to go to CDRH for an answer?

Erica

---

**From:** Marsh, Jordan <JMarsh@governor.sc.gov>

**Sent:** Tuesday, March 31, 2020 9:11 AM

To: IGA <IGA@fda.hhs.gov>

Subject: FW: (b)(4) mter, SC Manufacturing Company Information

We have a (b)(4) company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make (b)(4)?

Best,

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
[jmarsh@governor.sc.gov](mailto:jmarsh@governor.sc.gov)

---

From: Sarah Hearn <SarahHearn@schouse.gov>  
Sent: Wednesday, March 25, 2020 10:13 AM  
To: Marsh, Jordan <JMarsh@governor.sc.gov>  
Subject: [External] (b)(4) Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, Ms (b)(4) has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4)

Contact is

(b)(4)

cell

(b)(6)

Best to call

(b)(4)

cell. We currently manufacture

(b)(4)

(b)(4)

We sell

(b)(4)

Due to many of the retail stores closing, we

have decided to convert the factory over to making PPE.

First, we are currently set up to make

(b)(4)

(b)(4)

(b)(4)

Second, we are planning to make face masks. I have already started ordering the supplies for these

(b)(4)



(b)(4)

(b)(4) I have not started any research on those items yet. Any help on how to make them and approved (b)(4) would be very useful. I have spoken to a vendor that I buy supplies from for our (b)(4) and she said they have the (b)(4) Need to make sure FDA approves before I order it. Our plan is to (b)(4)

(b)(4)

In conclusion, I am working diligently to get this project up and running. I just need the approval from FDA on (b)(4) and a connection to sell these products. Any assistance, guidance, or advice will be greatly appreciated.

Thank You,

(b)(4)

Sarah Hearn

Research/Budget Analyst

Ways and Means Committee

S.C. House of Representatives

(803) 734-1577

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/1/2020 11:46:23 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: [External: (b)(4)] SC Manufacturing Company Information

Thank you!!!

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 11:46 AM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** FW: [External: (b)(4)] SC Manufacturing Company Information

Hi Jennifer,

The question below is about (b)(4). I have the CDRH website regarding (b)(4) but I haven't seen anything related to (b)(4) and COVID. Any assistance you can provide with an answer would be greatly appreciated.

Erica

---

**From:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Sent:** Tuesday, March 31, 2020 9:11 AM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** FW: [External: (b)(4)] SC Manufacturing Company Information

We have a (b)(4) company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make (b)(4)

Best,

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
jmarsh@governor.sc.gov

---

**From:** Sarah Hearn <SarahHearn@schouse.gov>  
**Sent:** Wednesday, March 25, 2020 10:13 AM  
**To:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Subject:** [External: (b)(4)] Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, Ms. (b)(4) has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4)

Contact is

(b)(4)

cell

(b)(6)

Best to call:

(b)(4)

cell. We currently manufacture

(b)(4)

(b)(4)

Due to many of the retail stores closing, we

have decided to convert the factory over to making PPE.

First, we are currently set up to make

(b)(4)

(b)(4)

be used. Second, we are planning to make face masks. I have already started ordering the supplies for these

(b)(4)

(b)(4) I have not started any research on those items yet. Any help on how to make them and approved (b)(4) would be very useful. I have spoken to a vendor that I buy supplies from for our (b)(4) and she said they have (b)(4) Need to make sure FDA approves before I order it.

Our plan is to

(b)(4)

(b)(4)

In conclusion, I am working diligently to get this project up and running. I just need the approval from FDA on the (b)(4) and a connection to sell these products. Any assistance, guidance, or advice will be greatly appreciated.

Thank You

(b)(4)

Sarah Hearn  
Research/Budget Analyst  
Ways and Means Committee  
S.C. House of Representatives  
(803) 734-1577

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 4/1/2020 11:52:12 AM  
**To:** JMarsh@governor.sc.gov  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Good morning Jordan,

On behalf of FDA's Intergovernmental Affairs (IGA) team, thank you for your inquiry regarding guidelines for making (b)(4) beds.

We will make every effort to respond to your question in a timely manner, but due to the COVID-19 pandemic, we may be delayed in responding.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Sent:** Tuesday, March 31, 2020 9:11 AM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

We have (b)(4) company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make (b)(4)

Best,

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
jmarsh@governor.sc.gov

---

**From:** Sarah Hearn <SarahHearn@schouse.gov>  
**Sent:** Wednesday, March 25, 2020 10:13 AM

To: Marsh, Jordan <JMarsh@governor.sc.gov>  
Subject: [External] (b)(4) Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, Ms. (b)(4) Zell has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4) Contact is  
(b)(4) cell (b)(6) Best to call (b)(4) cell. We currently manufacture (b)(4)  
(b)(4) Due to many of the retail stores closing, we  
have decided to convert the factory over to making PPE.

First, we are currently set up to make (b)(4)  
(b)(4)

(b)(4) Second, we are planning to make face masks. I have already started ordering the supplies for these

(b)(4)

(b)(4) I have not started any research on those items yet. Any help on how to make them and approved  
(b)(4) would be very useful. I have spoken to a vendor that I buy supplies from for our (b)(4) and she said  
they have the (b)(4) Need to make sure FDA approves before I order it.

Our plan is to (b)(4)  
(b)(4)

In conclusion, I am working diligently to get this project up and running. I just need the approval from FDA on  
the (b)(4) and a connection to sell these products. Any assistance, guidance, or advice will be greatly  
appreciated.

Thank You,  
(b)(4)

Sarah Hearn  
Research/Budget Analyst  
Ways and Means Committee  
S.C. House of Representatives

(803) 734-1577

---

**From:** Lott, Valerie [valerie.lott@dhhs.nc.gov]  
**Sent:** 4/1/2020 3:29:07 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: [External] Update on KN-95

Thank you Karen. We have seen some suspicious KN95 certificates, but trying to be vigilant.

I appreciate your willingness to assist us in this matter.

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health, Epidemiology Section  
North Carolina Preparedness and Response  
225 N. McDowell St.  
1902 MSC  
Raleigh, NC 27699-1900  
919-546-1823-office  
(b)(6) cell  
919-715-2246-fax  
**888-820-0520 (PHP&R 24/7 On-call)**  
Valerie.Lott@dhhs.nc.gov



---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 2:51 PM  
**To:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** [External] Update on KN-95

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [report.spam@nc.gov](mailto:report.spam@nc.gov)

Hi Valerie-

Still waiting for an answer on the labeling question but here's the latest info I've seen on KN95s:

Under the non-NIOSH approved respirator [EUA](#), we accept marketing authorization from several countries who have similar standards to NIOSH. Although China is one of them we did not include them on our list due to challenges in determining the authenticity of imported product and we have already encountered fraudulent products identified as KN95s. FDA is not stopping the importation of KN95s from China but cannot assure the performance and quality of individual shipments. Importers of the products may wish to verify certification, origin and chain of custody. So FDA is not stopping KN95s from being imported but our experience with fraud, etc. in this space made it clear that they should

not be part of the umbrella EUA. FDA is not the only nation that cited issues with these masks - we have since become aware that Dutch health authorities recalled 600,000 defective Chinese-made masks.

Meanwhile, hope you're hanging in there!

Karen

---

**From:** Meister, Karen G  
**Sent:** Tuesday, March 31, 2020 8:14 PM  
**To:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Subject:** RE: [External] Personal Protection Equipment

Good question. I will ask and probably have to get back to you tomorrow.

Thanks for your patience.

Karen

---

**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Sent:** Tuesday, March 31, 2020 7:54 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Re: [External] Personal Protection Equipment

Thank you so much Karen. I really do appreciate you getting back to me so quickly. Does each respirator have to be labeled or just the box they come in?

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health  
Public Health Preparedness and Response Branch  
NC Department of Health and Human Services

919-546-1823-office

(b)(6) cell

919-715-2246- fax

Valerie.Lott@dhhs.nc.gov

888-820-0520 (PHP&R 24/7 On-call)

225 N. McDowell St.  
1902 Mail Service Center  
Raleigh, NC 27699-1900



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Sent from my iPhone

On Mar 31, 2020, at 7:32 PM, Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)> wrote:

CAUTION: External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [report.spam@nc.gov](mailto:report.spam@nc.gov)

Hi Valerie-

Thanks for talking with me. As we discussed, following is some information on personal protection equipment:

Please see the following FDA website regarding emergency use authorizations for medical devices issued in connection with the corona virus: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>.

Last week, FDA issued guidance on Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings.

On March 30, FDA issued guidance on Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of gowns, other apparel, and gloves and helping to expand the availability of surgical apparel for health care professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency.

FDA does not object to marketing and distribution of gown and surgical apparel products in the healthcare setting without prior FDA 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

**Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let me know if you have additional questions. We know this is a difficult time.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office  
(b)(6) mobile*

---

**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Sent:** Tuesday, March 31, 2020 3:31 PM  
**To:** Deviceshortages <Deviceshortages@fda.hhs.gov>  
**Subject:** KN95

Hello,

Our state has purchased KN95s from a vendor after referencing the CDC's website "Strategies for Optimizing PPE...". Some of the vendors are being stopped at customs because the KN95s are not FDA approved devices. Please advise.

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health, Epidemiology Section  
North Carolina Preparedness and Response  
225 N. McDowell St.  
1902 MSC

Raleigh, NC 27699-1900

919-546-1823-office

(b)(6) cell

919-715-2246-fax

**888-820-0520 (PHP&R 24/7 On-call)**

Valerie.Lott@dhhs.nc.gov

<image001.png>

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Email correspondence to and from this address is subject to the North Carolina Public Records Law and may be disclosed to third parties by an authorized State official. Unauthorized disclosure of juvenile, health, legally privileged, or otherwise confidential information, including confidential information relating to an ongoing State procurement effort, is prohibited by law. If you have received this email in error, please notify the sender immediately and delete all records of this email.

---

**Sent:** 4/1/2020 3:54:04 PM  
**To:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: [External] Sumter, SC Manufacturing Company Information

Hi Akeisha,

Forgot to loop you in on this. I just sent the request to Vanessa Williams to triage an answer for us.

Erica

---

**From:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 3:52 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: [External] Sumter, SC Manufacturing Company Information

Hello Erica,

IMG Planning will route this inquiry to the appropriate office for follow-up.

Thank you.

Vanessa Williams  
RFI Triage  
Planning Section  
FDA COVID-19 IMG  
Office: 301-796-8262  
Cell: (b)(6)  
24-Hour Telephone: 301-796-8240 or 866-300-4374  
email: [vanessa.williams@fda.hhs.gov](mailto:vanessa.williams@fda.hhs.gov)

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---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 3:48 PM  
**To:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: [External] Sumter, SC Manufacturing Company Information

Hi Vanessa,

Below is a question from SC regarding mattresses for hospital beds. Any assistance with getting an answer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** White, Erica

**Sent:** Wednesday, April 1, 2020 11:46 AM

**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** FW: [External] Sumter, SC Manufacturing Company Information

Hi Jennifer,

The question below is about hospital beds. I have the CDRH website regarding hospital beds, but I haven't seen anything related to beds and COVID. Any assistance you can provide with an answer would be greatly appreciated.

Erica

---

**From:** Marsh, Jordan <JMarsh@governor.sc.gov>

**Sent:** Tuesday, March 31, 2020 9:11 AM

**To:** IGA <IGA@fda.hhs.gov>

**Subject:** FW: [External] Sumter, SC Manufacturing Company Information

We have a mattress company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make hospital beds?

Best,

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
jmarsh@governor.sc.gov

---

**From:** Sarah Hearn <SarahHearn@schouse.gov>  
**Sent:** Wednesday, March 25, 2020 10:13 AM  
**To:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Subject:** [External] Sumter Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, (b)(4) has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4), (b)(6)

(b)(4)

Sarah Hearn  
Research/Budget Analyst

Ways and Means Committee  
S.C. House of Representatives  
(803) 734-1577

---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/1/2020 8:29:47 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gomez]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for April 1, 2020

---

**From:** Legislation <Legislation@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 8:29 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 1, 2020

The FDA Office of Legislation would like to bring to your attention update on the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [legislation@fda.hhs.gov](mailto:legislation@fda.hhs.gov) for further information.  
Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data Now Available: In response to the COVID-19 pandemic, the FDA—in collaboration with the Centers for Disease Control and Prevention (CDC), the Biodefense and Emerging Infections Research Resources Repository (BEI Resources) and the Institute for Genome Sciences at the University of Maryland and the National Center for Biotechnology Information (NCBI)—developed quality-controlled, reference sequence data for the SARS-CoV-2 reference strain for the United States. Availability of traceable and quality-controlled data will help test developers and vaccine developers:
  - Expedite development of medical countermeasures.
  - Identify new or more stable targets for future tests.
  - Enable in silico confirmation of targets.
  - Support development of synthetic reference material.
  - Enable viral population/quasi species analysis.
- The FDA issued a Constituent Update regarding guidance it released today to provide temporary flexibility to chain restaurants and similar retail food establishments currently required to provide nutrition information, including calories, on menus and menu boards.
- The FDA is continuing to issue warning letters to companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. FDA and FTC issued a warning letter to Neuro XPF, which sells cannabidiol (CBD) products in the U.S. with the misleading claim these products can mitigate, prevent, treat, diagnose, or cure COVID-19. The agency will continue to pursue those that place public health at risk.



- Diagnostics update to date: During the COVID-19 pandemic, the FDA has worked with more than 220 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus. To date, 23 emergency use authorizations have been issued for diagnostic tests. On March 31<sup>st</sup> FDA issued an EUA that authorizes eligible molecular-based laboratory developed tests, or LDTs, that are developed and used by a single CLIA high complexity laboratory. Under this EUA, FDA has authorized Yale New Haven Hospital's SARS-CoV-2 PCR test. Additionally, the FDA has been notified that more than 110 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance. The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**From:** Brown, Akeisha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=802C3F43976C4EAE88F559C26CB51BE5-AKEISHA.BRO]  
**Sent:** 4/1/2020 11:48:55 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Will log this in tracker.

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 4:14 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

FYI- she's in planning triage so I think it means she determines where to send it in operations to get us an answer!

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 3:56 PM  
**To:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Hi Akeisha,

Forgot to loop you in on this. I just sent the request to Vanessa Williams to triage an answer for us. She does RFI Triage in the Planning Section of the FDA COVID-19 IMG group. I have no idea what all of that means, but I wanted to share it as an update.

Erica

---

**From:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 3:52 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Hello Erica,

IMG Planning will route this inquiry to the appropriate office for follow-up.

Thank you.

Vanessa Williams  
RFI Triage  
Planning Section  
FDA COVID-19 IMG

Office: 301-796-8262

Cell: (b)(6)

24-Hour Telephone: 301-796-8240 or 866-300-4374

email: [vanessa.williams@fda.hhs.gov](mailto:vanessa.williams@fda.hhs.gov)

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 think you have received this e-mail message in error, please e-mail the sender immediately at [vanessa.williams@fda.hhs.gov](mailto:vanessa.williams@fda.hhs.gov)

---

**From:** White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>

**Sent:** Wednesday, April 1, 2020 3:48 PM

**To:** Williams, Vanessa <[Vanessa.Williams@fda.hhs.gov](mailto:Vanessa.Williams@fda.hhs.gov)>

**Cc:** Tomasello, Jennifer <[Jennifer.Tomasello@fda.hhs.gov](mailto:Jennifer.Tomasello@fda.hhs.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>

**Subject:** FW: [External: (b)(4)] SC Manufacturing Company Information

Hi Vanessa,

Below is a question from SC regarding (b)(4) for hospital beds. Any assistance with getting an answer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** White, Erica

**Sent:** Wednesday, April 1, 2020 11:46 AM

**To:** Tomasello, Jennifer <[Jennifer.Tomasello@fda.hhs.gov](mailto:Jennifer.Tomasello@fda.hhs.gov)>

**Cc:** Pennington, Caitlin <[Caitlin.Pennington@fda.hhs.gov](mailto:Caitlin.Pennington@fda.hhs.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>; Paulos, Lauren <[Lauren.Paulos@fda.hhs.gov](mailto:Lauren.Paulos@fda.hhs.gov)>

**Subject:** FW: [External: (b)(4)] SC Manufacturing Company Information

Hi Jennifer,

The question below is about (b)(4) I have the CDRH website regarding (b)(4) but I haven't seen anything related to (b)(4) and COVID. Any assistance you can provide with an answer would be greatly appreciated.

Erica

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**From:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Sent:** Tuesday, March 31, 2020 9:11 AM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

We have a (b)(4) company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make (b)(4) }

Best,

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
jmarsh@governor.sc.gov

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**From:** Sarah Hearn <SarahHearn@schouse.gov>  
**Sent:** Wednesday, March 25, 2020 10:13 AM  
**To:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Subject:** [External] (b)(4) Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, Ms (b)(4) has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4) Contact is (b)(4) cell: (b)(6) Best to call (b)(4) cell. We currently manufacture (b)(4) (b)(4) We sell to (b)(4) Due to many of the retail stores closing, we have decided to convert the factory over to making PPE. First, we are currently set up to make (b)(4) (b)(4) (b)(4) Second, we are planning to make face masks. I have already started ordering the supplies for these

**(b)(4)**

**(b)(4)** I have not started any research on those items yet. Any help on how to make them and approved **(b)(4)** would be very useful. I have spoken to a vendor that I buy supplies from for our **(b)(4)** and she said they have **(b)(4)**. Need to make sure FDA approves before I order it.

Our plan is to **(b)(4)**

**(b)(4)**

In conclusion, I am working diligently to get this project up and running. I just need the approval from FDA on **(b)(4)** and a connection to sell these products. Any assistance, guidance, or advice will be greatly appreciated.

Thank You.

**(b)(4)**

Sarah Hearn

Research/Budget Analyst

Ways and Means Committee

S.C. House of Representatives

(803) 734-1577

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/2/2020 9:08:41 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: URGENT REPLY - FACE MASKS AND RESPIRATORS

Fyi

Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner, OPPLIA  
U.S. Food and Drug Administration  
Work Landline: (301) 796-8916  
Work Cell phone: (240) 494-6228  
Personal Cell: (b)(6) (will return call on work cell)  
Email: Karen.meister@fda.hhs.gov

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**From:** COVID19 FDA IMPORT INQUIRIES <COVID19FDAIMPORTINQUIRIES@fda.hhs.gov>  
**Date:** April 2, 2020 at 8:33:22 AM EDT  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Subject:** FW: URGENT REPLY - FACE MASKS AND RESPIRATORS

Hello all,

Below please find an inquiry related to Domestic manufacturing and COVID-19.

Thanks,

Magda Karlsen  
COVID-19 DIO Team

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**From:** (b)(6)  
**Sent:** Wednesday, April 1, 2020 12:09 PM  
**To:** Deviceshortages <Deviceshortages@fda.hhs.gov>; COVID19 FDA IMPORT INQUIRIES <COVID19FDAIMPORTINQUIRIES@fda.hhs.gov>  
**Cc:** (b)(6)  
**Subject:** URGENT REPLY - FACE MASKS AND RESPIRATORS

Hello to whom it may concern.,

Our manufacturing factory in (b)(4) is trying to find out more information regarding any **liability** we will take on or any **necessary certifications** we need to have if we would convert our (b)(4) in our factory to produce respirator masks domestically in (b)(4)

I have read through all material online (Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency , Emergency Use Authorizations (EUAs) for Personal Protective Equipment, General background on EUAs can be found here, and available for manufacturers regarding importation) On your site in regards to EUA. We are still a bit unclear on the **specific liability and certifications** necessary to produce domestically.

Can we please speak with someone regarding this urgently? We would like to help the situation, but have not received a clear answer. Thank you in advance for you time. Please reach my cell at: (b)(6)

God bless,

**(b)(4)**

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**Sent:** 4/2/2020 11:27:27 AM  
**Subject:** Coronavirus Update: FDA Actions to Address Urgent Need for Blood

Good morning,

As part of the U.S. Food and Drug Administration's ongoing commitment to fight the Coronavirus Disease 2019 (COVID-19) pandemic, today the agency issued guidance for immediate implementation to address the urgent and immediate need for blood and blood components.

The COVID-19 pandemic has caused unprecedented challenges to the U.S. blood supply. Donor centers have experienced a dramatic reduction in donations due to the implementation of social distancing and the cancellation of blood drives.

Maintaining an adequate blood supply is vital to public health. Blood donors help patients of all ages – accident and burn victims, heart surgery and organ transplant patients and those battling cancer and other life-threatening conditions. The American Red Cross estimates that every two seconds, someone in the U.S. needs blood.

People who donate blood are part of our critical infrastructure industries. More donations are needed at this time and we hope people will continue to take the time to donate blood. We have also encouraged, and continue to encourage, state and local governments to take into account the essential nature of donating blood - and that it can be done safely and consistently within social distancing guidelines - when considering travel and business restrictions, and we encourage them to communicate that to their citizens.

At the FDA, we want to do everything we can to encourage more blood donations, which includes revisiting and updating some of our existing policies to help ensure we have an adequate blood supply, while still protecting the safety of our nation's blood supply.

Based on recently completed studies and epidemiologic data, the FDA has concluded that current policies regarding certain donor eligibility criteria can be modified without compromising the safety of the blood supply. Therefore, the FDA is revising recommendations in several guidances regarding blood donor eligibility. These changes are being put forth for immediate implementation and are expected to remain in place after the COVID-19 pandemic ends, with any appropriate changes based on comments we receive and our experience implementing the guidances. At this time, the alternatives to certain donor eligibility requirements being provided generally will apply only for the duration of the declared pandemic.

More information on this announcement can be found at this link:

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov





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**Sent:** 4/2/2020 2:03:29 PM  
**Subject:** FW: FDA letter re: EUA NY ventilator  
**Attachments:** Incoming Masks Letter 3.10 Final.pdf; Outgoing HHS Response to NYC\_ Mayor De Blasio letter\_SNS\_3.30.20 (1).docx

Hello Everyone,

HHS has requested FDA review and clear the attached response letter to NYC Mayor De Blasio. Both, the incoming letter from Mayor De Blasio and HHS's draft response, are attached.

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/3/2020 7:15:06 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirlev@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 2, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken yesterday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- Yesterday, the [FDA announced](#) that it is revising recommendations in several guidances regarding blood donor eligibility. These changes are based on recently completed studies and epidemiological data, leading the FDA to

conclude that the policies could be modified without compromising the safety of the blood supply. The changes being announced to three guidances (HIV, malaria and CJD/vCJD) are for immediate implementation, and are expected to remain in place after the COVID-19 pandemic ends, with any appropriate changes based on comments we receive and our experience implementing the guidances. Additionally, the FDA is publishing a fourth guidance providing notice of alternatives to certain requirements regarding blood donor eligibility for the duration of the COVID-19 pandemic. The guidances are available on FDA's web site.

- Food update to date: the FDA released a public service announcement on food safety and the food supply. Consumers should rest assured that the FDA is on the job and working tirelessly to keep the American food supply among the safest in the world. The agency still reports no widespread food shortages or food safety issues.
- Yesterday, the FDA and Federal Trade Commission (FTC) issued warning letters to three companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. With these warning letters, the FDA is exercising its authority to protect consumers from companies selling unapproved products and making false or misleading claims during the COVID-19 pandemic.
  - One of the companies warned, Gaia's Whole Healing Essentials LLC., sells unapproved and misbranded colloidal silver products with misleading claims the products can build immunity for the treatment or prevention of COVID-19.
  - Another company warned, Homeomart Indibuy, offers homeopathic drug products for sale in the U.S. that are unapproved and misbranded with misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19.
  - The third company warned, Health Mastery Systems DBA Pure Plant Essentials, sells essential oils with misleading claims that the products are safe and/or effective for the treatment or prevention of COVID-19.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 240 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, 25 emergency use authorizations have been issued for diagnostic tests. Notably, the FDA issued an emergency use authorization, on April 1, 2020, to Cellex Inc.'s qSARS-CoV-2 IgG/IgM Rapid Test which is the first serology test to date to receive authorization to test for the presence of coronavirus antibodies. Cellex's labeling notes that test results from this serology test should not be used as the sole basis for diagnosis and can only aid in the diagnosis of patients in conjunction with a medical review of symptoms and results of other laboratory tests.
  - The FDA has been notified that more than 125 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.
- A new FDA Voices was issued: FDA Commissioned Corps Officers on the Front Line of COVID-19 Response. Almost 400 FDA Commissioned Corps officers have been deployed to aid in response to the pandemic. Among HHS agencies, the FDA is privileged to have the second highest number of Commissioned Corps officers serving in our ranks—more than 1,100 officers in total. This allows us to truly be on call 24/7 to protect America's food supply and essential medicines, and to ensure the safety of life-saving medical devices, vaccines and the blood supply during this pandemic. FDA's U.S. Public Health Service (USPHS) Commissioned Corps officers are highly-trained public health professionals who work nationally and internationally in careers such as medicine, veterinary sciences, dentistry, nursing, epidemiology and biomedical research to serve underserved and vulnerable communities.

#### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



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**Sent:** 4/3/2020 9:54:26 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Urgent: Sen. Feinstein Request re: States

Hi Karen,

In your response to Andy, you may want to mention that everyday we send the COVID 19 updates to State Health Departments and Gov Fed reps, we also send out

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Friday, April 3, 2020 9:49 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>  
**Subject:** Urgent: Sen. Feinstein Request re: States

IGA-

Sen. Murkowski would like to speak to the Commissioner about "FDA technical support for states. For example, assistance to health departments as they work to navigate numerous new product, technology, and manufacturing offers from industry."

Do you have any information on anything we are doing to liaise with states and/or departments of health?

**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



---

**Sent:** 4/3/2020 10:43:55 AM  
**To:** Shah, Nirav [Nirav.Shah@maine.gov]  
**CC:** Owsiak, Rita [Rita.Owsiak@maine.gov]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

This morning, in response to this evolving public health emergency and continued concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available that certain product classifications for imported disposable FFRs that are manufactured in China and not NIOSH-approved and for which data exists that supports the respirators' authenticity, are appropriate to protect the public health or safety.

Under this EUA, authorized respirators listed in Appendix A are authorized for use in healthcare settings by healthcare personnel when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

More information can be found at this link: [Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China](#)

---

**From:** White, Erica  
**Sent:** Wednesday, April 1, 2020 9:01 AM  
**To:** 'Shah, Nirav' <Nirav.Shah@maine.gov>  
**Cc:** 'Owsiak, Rita' <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

I am checking to see if you still have questions about the masks. If you would like to speak via phone today, please let me know your availability for a call.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** White, Erica  
**Sent:** Monday, March 30, 2020 11:55 AM  
**To:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

Thank you for your email below “regarding the use of so-called KN95 masks”. In order to better respond to your request and have a more effective dialogue, please reply to this email and let us know what questions you may have.

I also want to make you aware of the current FDA guidance which provides a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals during this pandemic. This guidance can be found at

<https://www.fda.gov/media/136449/download> .

Thank you for your email and we look forward to working with you.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Sent:** Sunday, March 29, 2020 3:14 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>  
**Subject:** N95 vs. KN95 question

Erica,

I'm the state health official for the state of Maine. I have a question regarding the use of so-called KN95 masks. I am aware of this recent guidance:

<https://www.fda.gov/media/136403/download>

But I still have a few remaining questions. Would it be possible to chat at some point in the next day or two?

Best,  
Nirav Shah

Nirav D. Shah, MD, JD

Director, Maine Center for Disease Control and Prevention



---

**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 4/3/2020 10:55:55 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: N95 vs. KN95 question

Good morning Karen,

Is this okay to send to people who've asked about the KN95 vs N95 masks? This is directly from the guidance document.

Good morning Dr. Shah,

This morning, in response to this evolving public health emergency and continued concerns about filtering facepiece respirator (FFR or respirator) availability, FDA concluded based on the totality of scientific evidence available that certain product classifications for imported disposable FFRs that are manufactured in China and not NIOSH-approved and for which data exists that supports the respirators' authenticity, are appropriate to protect the public health or safety.

Under this EUA, authorized respirators listed in [Appendix A](#) are authorized for use in healthcare settings by healthcare personnel when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

More information can be found at this link: [Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China](#)

The list of authorized respirators can be found at this link: [Appendix A](#)

The authorized respirators should be used in accordance with CDC's recommendations. For the most current CDC recommendations on optimizing respirator use, please visit CDC's webpage: [Strategies for Optimizing the Supply of N95 Respirators](#).

Thank you,

**Erica M. White, J.D.**

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[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** White, Erica  
**Sent:** Wednesday, April 1, 2020 9:01 AM

**To:** 'Shah, Nirav' <Nirav.Shah@maine.gov>  
**Cc:** 'Owsiak, Rita' <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

I am checking to see if you still have questions about the masks. If you would like to speak via phone today, please let me know your availability for a call.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** White, Erica  
**Sent:** Monday, March 30, 2020 11:55 AM  
**To:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

Thank you for your email below “regarding the use of so-called KN95 masks”. In order to better respond to your request and have a more effective dialogue, please reply to this email and let us know what questions you may have.

I also want to make you aware of the current FDA guidance which provides a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals during this pandemic. This guidance can be found at <https://www.fda.gov/media/136449/download> .

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Nirav Shah

Nirav D. Shah, MD, JD  
Director, Maine Center for Disease Control and Prevention

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/3/2020 12:06:14 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Update on KN-95

Hi Erica-

Would you please send Valerie the new information posted on this? Thanks!

---

**From:** Meister, Karen G  
**Sent:** Wednesday, April 01, 2020 2:51 PM  
**To:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Update on KN-95

Hi Valerie-

Still waiting for an answer on the labeling question but here's the latest info I've seen on KN95s:

Under the non-NIOSH approved respirator EUA, we accept marketing authorization from several countries who have similar standards to NIOSH. Although China is one of them we did not include them on our list due to challenges in determining the authenticity of imported product and we have already encountered fraudulent products identified as KN95s. FDA is not stopping the importation of KN95s from China but cannot assure the performance and quality of individual shipments. Importers of the products may wish to verify certification, origin and chain of custody. So FDA is not stopping KN95s from being imported but our experience with fraud, etc. in this space made it clear that they should not be part of the umbrella EUA. FDA is not the only nation that cited issues with these masks - we have since become aware that Dutch health authorities recalled 600,000 defective Chinese-made masks.

Meanwhile, hope you're hanging in there!

Karen

---

**From:** Meister, Karen G  
**Sent:** Tuesday, March 31, 2020 8:14 PM  
**To:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Subject:** RE: [External] Personal Protection Equipment

Good question. I will ask and probably have to get back to you tomorrow.

Thanks for your patience.

Karen

---

**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Sent:** Tuesday, March 31, 2020 7:54 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Re: [External] Personal Protection Equipment

Thank you so much Karen. I really do appreciate you getting back to me so quickly. Does each respirator have to be labeled or just the box they come in?

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health  
Public Health Preparedness and Response Branch  
NC Department of Health and Human Services

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225 N. McDowell St.  
1902 Mail Service Center  
Raleigh, NC 27699-1900



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Sent from my iPhone

On Mar 31, 2020, at 7:32 PM, Meister, Karen G <Karen.Meister@fda.hhs.gov> wrote:

**CAUTION:** External email. Do not click links or open attachments unless you verify. Send all suspicious email as an attachment to [report.spam@nc.gov](mailto:report.spam@nc.gov)

Hi Valerie-

Thanks for talking with me. As we discussed, following is some information on personal protection equipment:

Please see the following FDA website regarding emergency use authorizations for medical devices issued in connection with the corona virus: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>.

Last week, FDA issued guidance on Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of

filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings.

On March 30, FDA issued guidance on Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of gowns, other apparel, and gloves and helping to expand the availability of surgical apparel for health care professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency.

FDA does not object to marketing and distribution of gown and surgical apparel products in the healthcare setting without prior FDA 510(k) clearance if the product is labeled in the following manner:

- 1) The apparel is not labeled as "surgical"; rather it may be labeled as a "gown", "toga", "hood", etc.
- 2) It states it may be used when FDA cleared gowns or apparel are unavailable
- 3) Includes a recommendation against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 4) Includes a recommendation against use in a clinical setting where the infection risk level is high;
- 5) It makes no claims regarding flammability;
- 6) It makes no claims of antimicrobial or antiviral protection;
- 7) It makes no claims of infection prevention or reduction;
- 8) Contains a list of the body contacting materials.

In addition, FDA does not intend to object to marketing of gowns and other surgical apparel that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

#### **Masks:**

Surgical masks provide protection against large droplets, splashes or sprays of bodily or hazardous fluids. They do not provide the wearer with reliable protection from inhaling smaller airborne particles and are not considered respiratory protection. FDA regulates surgical masks as Class II devices and assesses them for liquid barrier protection among other things.

FDA recognizes the urgent need for face masks in the setting of the COVID-19 pandemic due to increased use and shortages in their availability.

FDA does not object to the marketing and distribution of face masks in the healthcare setting without prior 510(k) clearance if the product is labeled in the following manner:

- 1) It states it may be used when FDA cleared masks are unavailable;
- 2) It recommends against use in a surgical setting or where significant exposure to liquid bodily or other hazardous fluids may be expected;
- 3) It makes no claims of antimicrobial or antiviral protection;
- 4) It makes no claims of infection prevention or reduction;
- 5) It makes no claims regarding flammability
- 6) The labeling contains a list of the body contacting materials.
- 7) The mask is not labeled as a "surgical mask"; rather it may be labeled as a "face mask"

In addition, FDA does not intend to object to marketing of masks that meet the above criteria even if they are manufactured at facilities that do not meet 21 CFR 820.

Please let me know if you have additional questions. We know this is a difficult time.

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office  
(b)(6) mobile*

---

**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Sent:** Tuesday, March 31, 2020 3:31 PM  
**To:** Deviceshortages <Deviceshortages@fda.hhs.gov>  
**Subject:** KN95

Hello,

Our state has purchased KN95s from a vendor after referencing the CDC's website "Strategies for Optimizing PPE...". Some of the vendors are being stopped at customs because the KN95s are not FDA approved devices. Please advise.

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health, Epidemiology Section  
North Carolina Preparedness and Response  
225 N. McDowell St.  
1902 MSC  
Raleigh, NC 27699-1900  
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(b)(6) cell  
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**888-820-0520 (PHP&R 24/7 On-call)**  
Valerie.Lott@dhhs.nc.gov

<image001.png>

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---

**From:** Lott, Valerie [valerie.lott@dhhs.nc.gov]  
**Sent:** 4/3/2020 12:56:14 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: [External] FW: Update on KN-95

Erica,

I appreciate all the hard work you guys are doing at the FDA.

Stay strong and be safe!!

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health, Epidemiology Section  
North Carolina Preparedness and Response  
225 N. McDowell St.  
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---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 3, 2020 12:16 PM  
**To:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** [External] FW: Update on KN-95

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Good afternoon Valerie,

The FDA Intergovernmental Affairs team would like to bring your attention to today's updates regarding KN-95 respirators. On April 3, 2020, in response to continued respirator shortages, the FDA issued a new [EUA](#) for non-NIOSH-approved N95 respirators made in China, which makes KN-95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

The FDA also issued guidance to provide a policy to help expand the availability of general use face masks for the general public and respirators for healthcare professionals during this pandemic. The [guidance](#) applies to KN95 respirators as



well. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN-95 respirators, if they are on the Centers for Disease Control and Prevention (CDC) list of respirator alternatives during the COVID-19 pandemic.

**Additional Resources:**

FAQs on Shortages of Surgical Masks and Gowns.

[Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#)  
[Emergency Use Authorizations](#)

- [Letter of Authorization](#)
- [Appendix A: Authorized Respirators](#)

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** Meister, Karen G

**Sent:** Wednesday, April 01, 2020 2:51 PM

**To:** Lott, Valerie <[valerie.lott@dhhs.nc.gov](mailto:valerie.lott@dhhs.nc.gov)>

**Cc:** White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>

**Subject:** Update on KN-95

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Meanwhile, hope you're hanging in there!

Karen

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Karen

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Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office  
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**To:** Deviceshortages <Deviceshortages@fda.hhs.gov>  
**Subject:** KN95

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Valerie Lott, MPH, REHS  
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Valerie.Lott@dhhs.nc.gov

<image001.png>

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 4/4/2020 10:37:12 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Re: N95 vs. KN95 question

It was a nice “thank you”. Most of the states I’ve dealt with have been very pleasant. Demanding, but pleasant and friendly.

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** April 3, 2020 at 5:36:54 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: N95 vs. KN95 question



---

**From:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Sent:** Friday, April 03, 2020 5:32 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

Thank you so much for this follow up – very helpful and I’m so impressed that you thought to email this to me!

Nirav

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 3, 2020 11:34 AM  
**To:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

**EXTERNAL: This email originated from outside of the State of Maine Mail System. Do not click links or open attachments unless you recognize the sender and know the content is safe.**

Good morning Dr. Shah,

The FDA Intergovernmental Affairs team would like to bring your attention to today’s updates regarding KN-95 respirators. On April 3, 2020, in response to continued respirator shortages, the FDA issued a new EUA for non-NIOSH-approved N95 respirators made in China, which makes KN-95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic.

The FDA also issued guidance to provide a policy to help expand the availability of general use face masks for the general public and respirators for healthcare professionals during this pandemic. The guidance applies to KN95 respirators as well. It explains that for the duration of the pandemic, when FDA-cleared or NIOSH-approved N95 respirators are not available, the FDA generally would not object to the importation and use of respirators without an EUA, including KN-95 respirators, if they are on the Centers for Disease Control and Prevention (CDC) list of respirator alternatives during the COVID-19 pandemic.

**Additional Resources:**

[FAQs on Shortages of Surgical Masks and Gowns.](#)

[Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#)  
[Emergency Use Authorizations](#)

- [Letter of Authorization](#)
- [Appendix A: Authorized Respirators](#)

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** White, Erica  
**Sent:** Wednesday, April 1, 2020 9:01 AM  
**To:** 'Shah, Nirav' <[Nirav.Shah@maine.gov](mailto:Nirav.Shah@maine.gov)>  
**Cc:** 'Owsiak, Rita' <[Rita.Owsiak@maine.gov](mailto:Rita.Owsiak@maine.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

I am checking to see if you still have questions about the masks. If you would like to speak via phone today, please let me know your availability for a call.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** White, Erica  
**Sent:** Monday, March 30, 2020 11:55 AM  
**To:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: N95 vs. KN95 question

Good morning Dr. Shah,

Thank you for your email below "regarding the use of so-called KN95 masks". In order to better respond to your request and have a more effective dialogue, please reply to this email and let us know what questions you may have.

I also want to make you aware of the current FDA guidance which provides a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for health care professionals during this pandemic. This guidance can be found at <https://www.fda.gov/media/136449/download>.

Thank you for your email and we look forward to working with you.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



---

**From:** Shah, Nirav <Nirav.Shah@maine.gov>  
**Sent:** Sunday, March 29, 2020 3:14 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Owsiak, Rita <Rita.Owsiak@maine.gov>  
**Subject:** N95 vs. KN95 question

Erica,

I'm the state health official for the state of Maine. I have a question regarding the use of so-called KN95 masks. I am aware of this recent guidance:

<https://www.fda.gov/media/136403/download>



But I still have a few remaining questions. Would it be possible to chat at some point in the next day or two?

Best,  
Nirav Shah

Nirav D. Shah, MD, JD  
Director, Maine Center for Disease Control and Prevention

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/6/2020 8:02:43 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 3, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken Friday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration Friday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA [announced](#) that it is leading an effort, working collaboratively with government, industry and academic partners, to develop and implement a protocol that will provide convalescent plasma to patients in need across the

country who may not have access to institutions with clinical trials in place. Convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19. This collaboration, involving BARDA, the American Red Cross and the Mayo Clinic, will allow for a simplified process for health care providers that will help ensure patient safety while allowing for the collection of needed information about product efficacy. The FDA anticipates that the effort will be able to move thousands of units of plasma to patients who need them in the coming weeks.

- The FDA posted an [FAQ](#) answering whether respirators approved under standards used in other countries, such as KN95s, can be used in the US during the COVID-19 pandemic. The short answer is yes. In response to continued respirator shortages, the FDA also issued a new [Emergency Use Authorization \(EUA\)](#) for non-NIOSH-approved respirators made in China, which makes KN95 respirators eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic. Lastly, the FDA revised an [immediately in effect guidance](#) to help expand the availability of general use face masks for the general public and respirators (including N95 and KN95) for health care professionals during this pandemic.
- To help minimize the potential impact of the COVID-19 pandemic on new animal drug development, the FDA [issued guidance with recommendations](#) for sponsors conducting ongoing studies to support new animal drug development. These recommendations are designed to help ensure the safety of animals, their owners, and study personnel, maintain compliance with good laboratory practice regulations and good clinical practices, and maintain the scientific integrity of the data during the COVID-19 pandemic. It also addresses questions regarding CVM's coordination with foreign regulatory authorities during the pandemic. The guidance aligns with similar [recommendations](#) for sponsors of human drugs, biologics and medical devices released in March.
- The FDA announced it will begin requesting that importers send records required under the Foreign Supplier Verification Programs for Importers of Food for Humans and Animals (FSVP) rule electronically (or through other prompt means) to the agency as it shifts to conducting these inspections remotely during the COVID-19 public health emergency.
- The FDA is further extending the comment period for the Laboratory Accreditation for Analyses of Foods proposed rule by an additional 90 days. The comment period had previously been extended until April 6, 2020. However due to the ongoing coronavirus public health emergency, the comment period will now close July 6, 2020.
- The FDA released a [guidance document, Temporary Policy Regarding Packaging and Labeling of Shell Eggs Sold by Retail Food Establishments During the COVID-19 Public Health Emergency](#), to provide temporary flexibility regarding the packaging and labeling of shell eggs sold to consumers in retail food establishments.
- **Diagnostics update to date:**
  - During the COVID-19 pandemic, the FDA has worked with more than 240 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, 28 [emergency use authorizations](#) have been issued for diagnostic tests.
  - The FDA has been notified that more than 125 laboratories have begun testing under the policies set forth in our [COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance](#).
  - The FDA also continues to keep its [COVID-19 Diagnostics FAQ](#) up to date.

#### **Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/7/2020 2:54:21 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]  
**Subject:** FW: FDA Media Inquiry Clearance: Gastroenterology & Endoscopy News - EtO

fyi

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**From:** Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>  
**Sent:** Monday, April 06, 2020 9:03 PM  
**To:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Cc:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Subject:** FDA Media Inquiry Clearance: Gastroenterology & Endoscopy News - EtO

For OCC review please –

**Reporter:** Alison McCook  
**Outlet:** Gastroenterology & Endoscopy News  
**Deadline:** EOD Monday, April 6  
**Background:**

Reporter is writing a story for Gastroenterology & Endoscopy News about the shortages of ethylene oxide sterilization, and how that's been affected by the COVID-19 pandemic. She sent some questions to the EPA, which she says she saw is trying to increase capacity in Georgia, and EPA directed her to FDA.

**Questions:**

1. I understand that the healthcare system was facing an underlying stress from the shortage of ETO sterilization. How has this been exacerbated and/or affected by the COVID-19 pandemic?

(b)(5)

2. I have heard some facilities are trying to reuse single-use devices and/or PPE. What methods can they use to sterilize and/or disinfect them, and are these efforts being affected by the ETO shortages?

**(b)(5)**

3. Our publication focuses on gastroenterology and endoscopy. How is this all playing out in this specific field of medicine?

**(b)(5)**

**Brittney Manchester**  
*Press Officer*

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301-796-1026 | Cell: (b)(6)  
brittney.manchester@fda.hhs.gov



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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/7/2020 3:24:29 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** Good language - COVID-19 innovations

fyi

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**From:** Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>  
**Sent:** Saturday, April 04, 2020 5:54 PM  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Subject:** Media Inquiry FYI: PBS Newshour - COVID-19 innovations

Flagging this cleared inquiry for the JIC. Thanks!

**Reporter:** Catherine Wise

**Media Outlet:** PBS Newshour

**Background:**

Catherine is a producer with the national PBS NewsHour and is writing a story for their website about COVID-19 innovations at colleges and universities. She says: "There's a lot going on as you know and many researchers/students are working on new PPE, medical devices, apps, etc. I would like to include the perspective of the FDA in this story. How does the FDA view the innovation happening around the country? Any concerns about how these devices may work in the field if they've been developed quickly and not undergone rigorous testing? How many applications have you been receiving for rapid review? Those kinds of things."

**Response:**

The FDA continues to take creative and flexible approaches to address access to critical medical products in response to COVID-19. During the COVID-19 pandemic, the need for certain medical devices, including personal protective equipment (PPE), may outpace the supply available to health care organizations because of the high demand and overall interruptions to the global supply chain. Individuals, communities, and companies across the country are stepping up to help increase manufacturing, deploy innovative solutions, and even produce items for donation as stop-gap measures to address shortages, protect workers and the public, and help slow the spread of coronavirus. Researchers at academic institutions, non-traditional manufacturers, communities of makers, and individuals are banding together to support and fill local and national needs. The FDA is actively engaged across this spectrum and developing ways to assist and support people who are looking for ways to help their communities in these ways. The goal is to enable and empower people to make a positive impact in the ways they are able, while ensuring their efforts and outputs are safe. For example, the FDA is working in partnership with the NIH, VA, and America Makes to support non-traditional manufacturing approaches, such as 3D printing, to address device shortages including ventilator parts and PPE. In collaboration with other public health agencies, the FDA is also exploring additional routes of engagement with state and community leaders to understand new, creative, and non-traditional means of addressing critical medical device needs.

The FDA is also committed to providing regulatory flexibility and helping facilitate access to critical medical products during this pandemic. One way we are facilitating access to critical medical products is through Emergency Use Authorizations (EUAs). Under EUAs, the FDA determines, among other elements, if it is reasonable to believe that the product may be effective and that the known and potential benefits outweigh the known and potential risks. More information about EUAs and lists of devices that have been authorized by FDA are available here: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>. Certain EUAs include appendices with lists of multiple devices covered under the single authorization. Many more products are available without EUAs as a result of FDA's flexible policies for the COVID-19

pandemic. Please see COVID-19 related guidance documents here: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>. Under these policies, many products are being used in the national response to COVID-19 without prior authorization or through further streamlined processes.

**Brittney Manchester**

*Press Officer*

Office of Media Affairs

Office of External Affairs

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 4/7/2020 3:25:33 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** More good language - shortage of PPE & supply chain

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**From:** Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>  
**Sent:** Saturday, April 04, 2020 5:51 PM  
**To:** 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>  
**Subject:** Media Inquiry FYI: WSJ - shortage of PPE & supply chain

Flagging this cleared inquiry for the JIC. Thanks!

**Reporter:** Tom Burton

**Media Outlet:** The Wall Street Journal

**Background:**

Reporter says he's hearing about the dire shortage of PPE at hospitals. "And I was kind of incredulous to learn that Suburban Hospital is asking people to sew masks for them. (!!!) Does FDA have any role in fixing that supply chain, and if so, are there any smart stories we can be writing about what you and others are doing? Or is it kind of out of your hands once you approve certain masks and such"

**Response:**

As part of FDA's ongoing and aggressive commitment to address the coronavirus pandemic, we constantly surveil the global supply chain. To help address availability concerns, FDA is focused on helping facilitate the development of medical products and working with state and local officials to help ensure the necessary supplies are available to care for and protect our most vulnerable populations.

We've worked with Federal and state partners and have taken steps in the context of this pandemic to help expand the availability of respirators, masks and other personal protective equipment (PPE).

For instance, we are partnering with the Federal Emergency Management Agency (FEMA) on supply chain issues, including importation of needed medical products to support the U.S. response. Please see: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-further-steps-help-mitigate-supply-interruptions-food-and>

We've also recommended strategies to health care organizations and personnel to help conserve needed supply of PPE during this pandemic. For example, the FDA sent a letter to health care providers on conservation strategies: <https://www.fda.gov/medical-devices/letters-health-care-providers/surgical-mask-and-gown-conservation-strategies-letter-healthcare-providers>.

Moreover, the FDA is committed to providing regulatory flexibility and facilitating access to critical medical products during this crisis. One way we are facilitating access to critical medical products is through Emergency Use Authorizations (EUAs). Under EUAs, the FDA determines, among other elements, if it is reasonable to believe that the product may be effective and that the known and potential benefits outweigh the known and potential risks. More information about EUAs and the list of devices that have been authorized by FDA are available here, <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#coronavirus2019>. Certain EUAs include appendices with lists of multiple devices covered under the single authorization.

Specific to respirators, the FDA issued an Emergency Use Authorization (EUA) to Battelle Memorial Institute for its Battelle Decontamination System for use in decontaminating compatible single-use N95 respirators so they can be reused by health care personnel. The FDA is committed to working across government and with the private sector to find solutions fast.

The FDA also issued a new Emergency Use Authorization (EUA) for non-NIOSH-approved respirators made in China, which makes KN95 respirators and other respirators made in China eligible for authorization if certain criteria are met, including evidence demonstrating that the respirator is authentic. Additionally, the FDA revised an immediately in effect guidance to help expand the availability of general use face masks for the general public and respirators (including N95 and KN95) for health care professionals during this pandemic. We are flexible and are adapting to this pandemic, so that we can get essential medical devices to those in need to protect against COVID-19.

Many more products are available without EUAs as a result of FDA's flexible policies for this particular emergency. Most PPE, for example, do not have an EUA and we have provided recommendations that provide flexibility to manufacturers of many masks, gowns, and gloves when they distribute their products without prior authorization under our new policies. Please see COVID-19 related guidance documents here, which include FDA's COVID-19 policies related to PPE: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders>.

Individuals, communities, and companies across the country are stepping up to help increase manufacturing, deploy innovative solutions, and even produce items for donation as stop-gap measures to address shortages, protect workers and the public, and help slow the spread of coronavirus. Researchers at academic institutions, non-traditional manufacturers, communities of makers, and individuals are banding together to support and fill local and national needs. The FDA is actively engaged across this spectrum and developing ways to assist those who are looking for ways to help their communities in these ways. FDA's goal is to help enable and empower people to make a positive impact in the ways they are able, while ensuring their efforts and outputs are safe. For example, the FDA is working in partnership with the NIH, VA, and America Makes to coordinate on non-traditional manufacturing approaches, such as 3D printing, to address device shortages including ventilator parts and PPE. In collaboration with other public health agencies, the FDA is also exploring additional routes of engagement with state and community leaders to understand new, creative, and non-traditional means of addressing critical medical device needs. We've also been working with many non-traditional manufacturers, such as Hanes, Jockey, Ford, and GM to expand the availability of respirators and masks in short supply.

We appreciate Congress including the provision for additional device shortages authority during or in advance of a declared public health emergency in the CARES Act. The FDA looks forward to continuing to work with members of Congress to further expand these authorities so that we can address shortages in other situations as well. Such legislation would ensure the FDA has timely and accurate information about likely or confirmed national shortages of essential devices to enable FDA to take steps to promote the continued availability of devices of public health importance even when there is not a declared emergency, particularly as knowing of potential shortages in advance allows us to take steps to mitigate them before there is an emergency.

**Brittney Manchester**

Press Officer

Office of Media Affairs

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 4/7/2020 8:21:32 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Coronavirus (COVID-19) Update: Daily Roundup for April 6, 2020

Thanks!

(b)(6)

(b)(6)

(b)(6)

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 7, 2020 8:12 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for April 6, 2020

Thank you for doing these. It's a crazy time and I want you to know how much you are appreciated for all you do.

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**From:** IGA <IGA@fda.hhs.gov>  
**Sent:** Tuesday, April 07, 2020 8:10 AM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 6, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken yesterday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- On April 4, 2020, the FDA issued guidance on clinical electronic thermometers that immediately went into effect. Fever is a common symptom of COVID-19 and clinical electronic thermometers are an important screening and diagnostic tool to assist in the identification of those individuals who may be infected with COVID-19. The policy set forth in the guidance may help expand the availability of clinical electronic thermometers to address this public health emergency.
- On April 5, 2020, the FDA issued guidance on infusion pumps and accessories that immediately went into effect. The guidance aims to help ensure the availability of infusion pumps and accessories for patients who require continuous infusion of medications, nutrition, and other fluids and help foster technologies, such as remote capabilities, that maintain a safer physical distance between the health care provider and the patient.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 270 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, 28 emergency use authorizations have been issued for diagnostic tests.
  - The FDA has been notified that more than 145 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- Coronavirus Disease 2019 [COVID-19]

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

Erica.White@fda.hhs.gov



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**From:** Luebke, Yasemin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=10D526E5C46F47CE83978507A5365DE5-YASEMIN.LUE]  
**Sent:** 4/7/2020 10:20:48 AM  
**To:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gome]; Hattis, Daniel [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea12bdaa04f42f0afb9dd6abf39793a-Daniel.Hatt]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Nguyen, Michael A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd81ee5310745588f739376431ea14b-Michael.Ngu]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Price, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4f6e66e367574338b48eca70c18edda5-William.Pri]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Congressional inquiry re: Kevin Ferris  
**Attachments:** Ferris, Kevin\_FDAinquiry\_4.6.2020.pdf

fyi

---

**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Tuesday, April 7, 2020 9:21 AM  
**To:** Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Cc:** Legislation <Legislation@fda.hhs.gov>  
**Subject:** FW: Congressional inquiry re: Kevin Ferris

Hi Yasemin,

I think this is another inquiry for you – but looping in Lauren just in case.

Thanks!

Caitlin

---

**From:** George, Emily (Cornyn) <Emily\_George@cornyn.senate.gov>  
**Sent:** Monday, April 6, 2020 6:39 PM  
**To:** Legislation <Legislation@fda.hhs.gov>  
**Subject:** Congressional inquiry re: Kevin Ferris

Good afternoon,

Please see the attached congressional inquiry regarding Kevin Ferris.

Thanks,

EMILY GEORGE  
CONSTITUENT SERVICES LIAISON  
U.S. SENATOR JOHN CORNYN (TX)  
TEL: (972) 239-3349

FAX: (972) 239-2110



---

**Sent:** 4/8/2020 8:07:34 AM  
**To:** Hermann, Alexandria [Alexandria.Hermann@nj.gov]  
**Subject:** RE: EUAs

Good morning Alexandria,

Thank you for your email below regarding Emergency Use Authorizations submitted by Rutgers University for a COVID test based on saliva that could be done without swabs.

---

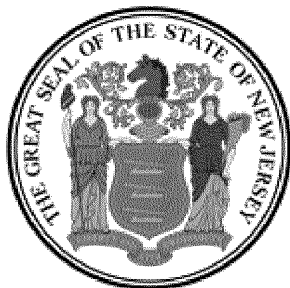
**From:** Hermann, Alexandria <Alexandria.Hermann@nj.gov>  
**Sent:** Tuesday, April 7, 2020 7:43 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** EUAs

Hi Erica,

I hope all is well with you and you are hanging in there! I wanted to check in to see if you had any information on two Emergency Use Authorizations submitted by Rutgers University for a COVID test based on saliva that could be done without swabs. The two numbers I have for them are: (EUA200090, EUA200091). If there's any additional information I can provide I'm happy to be helpful in any way. We are excited at the possibility of having a swabless test in the state where collection could be done in glass vials and have been told that they can scale up quickly.

Thanks!  
Alex

Alexandria L. Hermann  
Director of Federal Affairs  
Governor Phil Murphy  
444 North Capitol Suite NW Suite 201  
Washington, DC 20001  
O: (202) 638-0631  
C: (b)(6)





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**Sent:** 4/8/2020 9:42:20 AM  
**To:** Williams, Vanessa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b17deb4d55ad4258b9dfcc6336bf6ad0-VWILLIA1]; CDRH-NonDiagnosticEUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b31298151e33457eae63d331b684e15c-CDRH-NonDia]  
**CC:** Ellis, Patricia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dec0284840704f568a8b9f314058ad63-Patricia.El]; Aldridge, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f7761ef82074a45a6a58ac539b3dbb5-Megan.McCur]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; 2019-nCoV FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]  
**Subject:** RE: Clarification of FDA Ventilator EUA Policy

Good morning all,

Once there is a response, IGA can take the lead on getting in touch with Mr. Gatz.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Sent:** Wednesday, April 8, 2020 9:36 AM  
**To:** CDRH-NonDiagnosticEUA-Templates <CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov>  
**Cc:** Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Aldridge, Megan <Megan.Aldridge@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: Clarification of FDA Ventilator EUA Policy

Additionally, if possible, to ensure the explanation is delivered correctly, FEMA would prefer that FDA contact Mr. Gatz to provide the response.

Thank you.

Vanessa Williams  
RFI Triage  
Planning Section  
FDA COVID-19 IMG

Office: 301-796-8262

Cell: (b)(6)

24-Hour Telephone: 301-796-8240 or 866-300-4374

email: [vanessa.williams@fda.hhs.gov](mailto:vanessa.williams@fda.hhs.gov)

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---

**From:** Williams, Vanessa <[Vanessa.Williams@fda.hhs.gov](mailto:Vanessa.Williams@fda.hhs.gov)>

**Sent:** Wednesday, April 8, 2020 8:32 AM

**To:** CDRH-NonDiagnosticEUA-Templates <[CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov](mailto:CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov)>

**Cc:** Ellis, Patricia <[Patricia.Ellis@fda.hhs.gov](mailto:Patricia.Ellis@fda.hhs.gov)>; Aldridge, Megan <[Megan.Aldridge@fda.hhs.gov](mailto:Megan.Aldridge@fda.hhs.gov)>; White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>; 2019-nCoV FDA IMG Planning <[2019-nCoVFDAIMGPlanning@fda.hhs.gov](mailto:2019-nCoVFDAIMGPlanning@fda.hhs.gov)>

**Subject:** RFI: Clarification of FDA Ventilator EUA Policy

Good morning,

OK State's Secretary of Transportation Executive Director Tim J. Gatz, Oklahoma Turnpike Authority at (405)-425-3650 is seeking an explanation for the FDA guidance to help their response operations: specific to the Aeonmed VG70 as included in Appendix B to the EUA (details in email string below).

Thank you.

Vanessa Williams

RFI Triage

Planning Section

FDA COVID-19 IMG

Office: 301-796-8262

Cell: (b)(6)

24-Hour Telephone: 301-796-8240 or 866-300-4374

email: [vanessa.williams@fda.hhs.gov](mailto:vanessa.williams@fda.hhs.gov)

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---

**From:** Young, Lavern <[Lavern.Young@fema.dhs.gov](mailto:Lavern.Young@fema.dhs.gov)>

**Sent:** Tuesday, April 07, 2020 11:22 PM

**To:** Arsenault, Sam <[Samuel.Arsenault@fda.hhs.gov](mailto:Samuel.Arsenault@fda.hhs.gov)>

**Cc:** Young (COL Ret) Lavern <(b)(6)>; Stolar, Gerard <[Gerard.Stolar@fema.dhs.gov](mailto:Gerard.Stolar@fema.dhs.gov)>; Bordelon, Denise <[Denise.Bordelon@fema.dhs.gov](mailto:Denise.Bordelon@fema.dhs.gov)>; Pack, Eddie <[Eddie.Pack@fema.dhs.gov](mailto:Eddie.Pack@fema.dhs.gov)>

**Subject:** Clarification of FDA Policy

Mr. Arsenault,

We have another request for information. The state of OK request clarification on an FDA policy. They would like to know the following:

1. Is the FDA approval of and specific to the Aeonmed VG70 as included in Appendix B to the EUA limited to the COVID-19 pandemic specifically, thereby limiting the ability to return the critical care ventilator to or use for stockpile / supply enhancement for protection against a future reoccurrence of such an event?
2. If ultimately the machines were not used and were unable to be included in the stockpile for future use, would this represent any potential reimbursement risk?

If someone would call the Secretary of Transportation Executive Director Tim J. Gatz, Oklahoma Turnpike Authority at (405)-425-3650 and explain the FDA guidance it will help in their response operations. Let me know if there is any additional information you need. Thanks

L.Young

FEMA Region 6

(b)(6)

Begin forwarded message:

From: "Gatz, Tim" <tgatz@pikepass.com>

Date: April 7, 2020 at 6:11:32 PM CDT

To: Mark Gower <Mark.Gower@oem.ok.gov>

Cc: Gino DeMarco <Gino.DeMarco@travelok.com>, John Budd <John.Budd@gov.ok.gov>

Subject: [External] FDA Emergency Use Authorization for Ventilators for clarification

Mark,

The guidance on the ventilator FDA Emergency Use Authorization is a bit unclear to us in one aspect. Can you ask your FDA contact to advise us on the following issue?

Is the FDA approval of and specific to the Aeonmed VG70 as included in Appendix B to the EUA limited to the COVID-19 pandemic specifically, thereby limiting the ability to return the critical care ventilator to or use for stockpile / supply enhancement for protection against a future reoccurrence of such an event? Also, if ultimately the machines were not used and were unable to be included in the stockpile for future use, would this represent any potential reimbursement risk?

This clarification would be extremely useful to us in our decision making related to the acquisition of this product. Thank you for any assistance that you / the FDA can provide.

Tim J. Gatz

Secretary of Transportation

Executive Director

Oklahoma Turnpike Authority

(405)-425-3650

---

**Sent:** 4/8/2020 12:06:13 PM  
**To:** CDRH-EUA-Templates [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bf0733393d74e80a407946c10c53411-CDRH-EUA-Te]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Williams, Vanessa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b17deb4d55ad4258b9dfcc6336bf6ad0-VWILLIA1]; 2019-nCoV FDA IMG Planning [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8aa3f7699ef4e84b4b1a9541592d0cf-2019-nCoV F]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** FW: EUAs  
**Attachments:** EUA200090 Acknowledgment Letter.pdf; 2003-0357 ThermoFisher COVID-19 Detection Assay.PDF; 2019077 Frazier (For Research Use Only) IFU Insert SDNA-1000 v2.0.pdf; RCGL\_RUCDR\_Rutgers\_University\_EUA\_Saliva\_Thermo\_TaqPath\_COVID-19\_Combo\_Kit\_20200402.pdf; RCGL\_ThermoFisher\_Spectrum\_Saliva\_EUA\_FORM\_FDA\_3514\_20200402.pdf; SDS - Spectrum DNA Stabilizing Solution.pdf; EUA-TaqPath-COVID-19-Combo-Kit-Thermo-Fisher-HCP.pdf; RCGL\_ThermoFisher\_Taqpath\_EUA\_FORM FDA 3514\_20200328.pdf

Good afternoon,

Below is an email regarding the status of an EUA submitted by Rutgers University for a COVID test based on saliva that could be done without swabs.

---

**From:** Hermann, Alexandria <Alexandria.Hermann@nj.gov>  
**Sent:** Wednesday, April 8, 2020 11:55 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: EUAs

Hi Erica,

Thank you for the quick response. I believe I've attached the information that you are looking for but let me know if something is missing. We are really excited at the possibility of widespread deployment of this test so if there's anything we can do to help move this process along, just let me know.

And I hope everyone is doing well, all things considered.

Thanks again,  
Alex

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 8, 2020 8:11 AM  
**To:** Hermann, Alexandria <Alexandria.Hermann@nj.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** [EXTERNAL] RE: EUAs

Good morning Alexandria,

Thank you for your email below regarding Emergency Use Authorizations (EUA) submitted by Rutgers University for a COVID test based on saliva that could be done without swabs. If possible, please provide the information below to help us locate the EUA.

- Date when the sponsor sent information to FDA, and to what e-mail box it was sent to.
- If the sponsor received an auto-reply or other acknowledgement that we received their submission – and if so, what date they received it (if they can provide the e-mail, all the better).
- Is the company already in contact with FDA or working with us? If so, is there a contact they are working with at the Center?
- What information did they send to us? If staff have the submission or paperwork, even better.

This will help us to more quickly assess the status of the submissions and let you know when/if they were received, and if our review is in process.

Please let me know if anyone has questions; and thank you for your ongoing help and patience with us as we work to respond to all the inquiries we are receiving.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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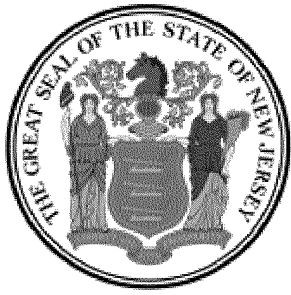
**From:** Hermann, Alexandria <Alexandria.Hermann@nj.gov>  
**Sent:** Tuesday, April 7, 2020 7:43 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** EUAs

Hi Erica,

I hope all is well with you and you are hanging in there! I wanted to check in to see if you had any information on two Emergency Use Authorizations submitted by Rutgers University for a COVID test based on saliva that could be done without swabs. The two numbers I have for them are: (EUA200090, EUA200091). If there's any additional information I can provide I'm happy to be helpful in any way. We are excited at the possibility of having a swabless test in the state where collection could be done in glass vials and have been told that they can scale up quickly.

Thanks!  
Alex

Alexandria L. Hermann  
Director of Federal Affairs  
Governor Phil Murphy  
444 North Capitol Suite NW Suite 201  
Washington, DC 20001  
O: (202) 638-0631  
C: (b)(6)



---

**Sent:** 4/9/2020 8:44:03 AM  
**To:** Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Erangers]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** Please review response to State Rep. Allen re: Sterigenics  
**Attachments:** (Clean) EtO Erick Allen Response.CDRH Cleared - 4-8-2020 - OCC ljr.docx

Good morning Erika

Attached for your review and clearance is the draft response to Georgia Representative Erick Allen regarding Sterigenics. The incoming letter is embedded in the draft response. Please review and clear at your earliest convenience.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



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**Sent:** 4/9/2020 10:54:32 AM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; 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]  
**Subject:** RE: Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Hi Jennifer,

Following up on this request.

---

**From:** White, Erica  
**Sent:** Thursday, April 2, 2020 4:20 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** FW: Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Good afternoon everyone,

FDA has been asked to prepare a response to Governor Kate Brown who writes about Oregon's need for sufficient personal protective equipment (PPE) and ventilators to assist with the COVID-19 epidemic. IGA has drafted an initial response. CDRH and the JIC, please review and clear the attached draft by COB, Monday, April 6.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** aimssystem@fda.hhs.gov <aimssystem@fda.hhs.gov>  
**Sent:** Thursday, April 2, 2020 7:21 AM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>; White, Erica



<Erica.White@fda.hhs.gov>

**Subject:** Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Note: Do NOT reply directly to this E-mail

A referral has been sent to your office by FDA/OC/OES/ on Correspondence Control # 2020-1492 requesting your assistance. A summary of the referral appears below. If you have any questions, please contact WANDA G. RUSS of FDA/OC/OES/.

**Action:** Prepare Response for Signature  
**Due Date:** Tuesday, April 7, 2020  
**Synopsis:** Department D/R for Commissioner Sig and Department R/C Governor Brown writes about Oregon's need for sufficient personal protective equipment (PPE) and ventilators to assist with the COVID-19 epidemic.

Please click the URL below to access the referral:

[http://aims.fda.gov/\\_cktoken/\\_ct\\_token.mainPage?p\\_token=sg8h1r70j03k570c3cm00000gzgfu60000158rjbmmgyp823301uis283r589ern](http://aims.fda.gov/_cktoken/_ct_token.mainPage?p_token=sg8h1r70j03k570c3cm00000gzgfu60000158rjbmmgyp823301uis283r589ern)

You can view the original correspondence by clicking the button 'View Orig Corr' (if available). After reviewing all the information provided, please acknowledge receipt of the referral by clicking either the ACCEPT button or the DECLINE button.

If you ACCEPT the referral, a new COMPLETE button is immediately displayed. You can either:

Click the COMPLETE button to complete the referral now

OR

You MUST retain this e-mail with the above URL until you have completed the referral request. Click the above URL again and click the COMPLETE button.

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/10/2020 8:18:12 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emais.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; christopher.walker@tn.gov  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 9, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken yesterday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA issued an immediately in effect guidance that outlines a temporary policy to help expand the availability of portable cryogenic oxygen and nitrogen containers. The demand for these critical medical gases is expected to rise during the pandemic and may result in a shortfall of portable cryogenic medical gas containers that meet regulatory requirements. The FDA does not intend to take enforcement action against firms that fill and distribute oxygen and nitrogen in portable cryogenic medical gas containers that do not comply with certain regulatory requirements, provided that alternative, specific safeguards are in place to prevent gas mix-ups. This guidance will be in effect until the end of the public health emergency.
- The FDA issued information and best practices for retail food stores, restaurants, and pick-up and delivery services during the pandemic to protect both workers and customers. Information shared includes smart food safety practices that employers can consider at any time. It is being issued in two convenient formats.
- Due to the potential risk of transmission of SARS-CoV-2 through Fecal Microbiota for Transplantation (FMT), the FDA updated information on its website pertaining to safety protections regarding the use of FMT, informing healthcare providers about screening donors for COVID-19 and exposure to and testing for SARS-CoV-2. This update follows a safety alert posted on March 23, 2020. The FDA has determined that additional protections are needed for any investigational use of FMT, whether under an investigational new drug application on file with FDA or under FDA's enforcement discretion policy.
- The FDA and Federal Trade Commission (FTC) issued a warning letter to one company for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The seller warned, Free Speech Systems LLC, DBA Infowars.com, offers unapproved and misbranded products for the prevention or treatment of COVID-19. There are currently no approved preventatives or treatments for COVID-19. Consumers should not purchase or take any product to prevent or treat COVID-19 unless it is prescribed by their health care provider and acquired from a legitimate source.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 270 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, 32 emergency use authorizations have been issued for diagnostic tests.
  - The FDA has been notified that more than 150 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

Thank you,

**Erica M. White, J.D.**  
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**Subject:** FDA Authorizes Blood Purification Device to Treat COVID-19

Good Morning

The U.S. FDA's Intergovernmental Affairs (IGA) team would like to bring to your attention two announcements issued today by the FDA.

The first announcement is FDA Authorizes Blood Purification Device to Treat COVID-19. FDA issued an emergency use authorization for a blood purification system to treat patients 18 years of age or older with confirmed Coronavirus Disease 2019 (COVID-19) admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure. This announcement can be found in its entirety at this link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-blood-purification-device-treat-covid-19>

The second announcement is FDA Issues Second Emergency Use Authorization to Decontaminate N95 Respirators. FDA also issued the second emergency use authorization to decontaminate compatible N95 or N95-equivalent respirators for reuse by health care workers in hospital settings. This EUA will support decontamination of approximately 750,000 N95 respirators per day in the U.S. This announcement can be found in its entirety at this link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-second-emergency-use-authorization-decontaminate-n95>

We hope this information is helpful to you.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
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**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 10, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken Friday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration Friday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA recently issued an emergency use authorization (EUA) for a blood purification system to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit with confirmed or imminent

respiratory failure. The FDA issued the EUA to Terumo BCT Inc. and Marker Therapeutics AG for their Spectra Optia Apheresis System and Depuro D2000 Adsorption Cartridge devices.

- The FDA recently issued an EUA to decontaminate compatible N95 or N95-equivalent respirators for reuse by health care workers in hospital settings. The FDA issued the EUA to STERIS Corporation for the STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems using the STERIS N95 Decontamination Cycle (non-lumen cycle), which uses vaporized hydrogen peroxide. This EUA will support decontamination of approximately 750,000 N95 respirators per day in the U.S.

- The FDA issued a guidance for immediate implementation for pharmacy compounders that experience shortages of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. PPE shortages have the potential to significantly impact the quality, purity and availability of drugs that are compounded for patients, including those in critical need. The guidance discusses how pharmacies may be able to preserve PPE if supplies are limited. Further, as a temporary measure to address the public health emergency posed by COVID-19, the agency is providing limited regulatory flexibility for compounders that cannot obtain sufficient supplies of PPE for sterile compounding, provided they adopt risk mitigation strategies as described in the guidance. FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available.

- Friday, the FDA and Federal Trade Commission issued a warning letter to one company for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The seller warned, Earthley Wellness DBA Modern Alternative Mama LLC., offers unapproved and misbranded herbal tinctures and herbal remedy products for the prevention or treatment of COVID-19. There are currently no approved preventatives or treatments for COVID-19. Consumers should not purchase or take any product to prevent or treat COVID-19 unless it is prescribed by their health care provider and acquired from a legitimate source.

- FDA Voices: A Perspective on the FDA's COVID-19 Response by Mitch Zeller, director of the FDA's Center for Tobacco Products, was issued. It provides a perspective of the FDA's "all-hands-on-deck" approach to tackling this pandemic. The FDA is integral in the fight against the coronavirus, using science and innovative approaches to take a broad range of actions that advance our nation's response.

- The FDA issued a Letter to Stakeholders advising people not use ivermectin intended for animals as a treatment for COVID-19 in humans. People should never take animal drugs, as the FDA has only evaluated their safety and effectiveness in the particular animal species for which they are labeled. These animal drugs can cause serious harm in people. People should not take any form of ivermectin unless it has been prescribed to them by a licensed health care provider and is obtained through a legitimate source.

- Diagnostics update to date:

- During the COVID-19 pandemic, the FDA has worked with more than 300 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.

- To date, 33 emergency use authorizations have been issued for diagnostic tests.

- The FDA has been notified that more than 170 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.

- The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

#### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)





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**From:** Gomez, Rachel A. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB9B744B3C3B4E3EA335C72BC527B8D8-RACHEL.GOME]  
**Sent:** 4/13/2020 8:48:51 AM  
**To:** JMarsh@governor.sc.gov  
**Subject:** MUSC's Covid testing swabs and medium shipment

Good morning Jordan from U.S. FDA's Intergovernmental Affairs (IGA)

Constituents who have a shipment of COVID-19 supplies held up at a port of entry should visit <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/importing-covid-19-supplies> for contact information and instructions. It includes an interactive map that importers can use to find the right office for their shipment, based on where the product is entering the United States. To speed assistance, they should provide the customs entry number (the 11-digit number they can get from their filer, not the airway bill), the port of entry, and other shipment details. If your constituent has already done this and needs additional help, **please email me the 11-digit entry number** and their U.S. Customs Broker contact information. Your constituent can locate this number on CBP Form 3461 Block #5, CBP Form 7501 block #1, or by contacting their Customs Broker/Shipping Representative.

**Rachel Gomez 郭瑞秋**  
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**From:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Sent:** Friday, April 10, 2020 4:28 PM  
**To:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
**Subject:** FW: [External] Fwd: Covid testing swabs and medium shipment  
**Importance:** High

Hi Darcie,

I need assistance with the FDA regarding a shipment for the Medical University of South Carolina that is being held up at the FDA Memphis office.

MUSC's COVID testing swabs and medium shipment (shipment FedEx tracking number (b)(4) have been waiting for FDA approval and release in Memphis, TN, since Wednesday. My understanding is that the FDA has selected this shipment for physical inspection. There is no required timeframe for them to complete this inspection. It cannot be released until FDA inspection is complete. The FDA Memphis office number is (901) 333-3520.

We need this shipment released and sent to MUSC asap. Let me know if you can help.

Thanks!

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
jmarsh@governor.sc.gov

**From:** Marsh, Jordan  
**Sent:** Friday, April 10, 2020 12:46 PM  
**To:** Sweatman, Mark <sweatmmc@musc.edu>  
**Cc:** Plowden, Mark <MPlowden@governor.sc.gov>  
**Subject:** RE: [External] Fwd: Covid testing swabs and medium shipment

Hi Mark,

I will run this down and follow up with an update this afternoon.

Best,  
Jordan

**From:** Sweatman, Mark <sweatmmc@musc.edu>  
**Sent:** Friday, April 10, 2020 11:09 AM  
**To:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Cc:** Plowden, Mark <MPlowden@governor.sc.gov>  
**Subject:** [External] Fwd: Covid testing swabs and medium shipment

Good morning, Jordan -

We have some swabs stuck in Memphis at the FDA Memphis office. Can you help?

Hope all is well with you.

Thanks,

Mark

Sent from my iPhone

Begin forwarded message:

**From:** "Goodlett, Lisa" <goodlettl@musc.edu>  
**Date:** April 10, 2020 at 7:41:52 AM EDT  
**To:** "Cawley, Patrick J." <cawleypj@musc.edu>, "Sweatman, Mark" <sweatmmc@musc.edu>  
**Subject:** Fwd: Covid testing swabs and medium shipment

Begin forwarded message:

**From:** "Rae, Karyn D." <raek@musc.edu>  
**Date:** April 10, 2020 at 7:24:16 AM EDT  
**To:** "Goodlett, Lisa" <goodlettl@musc.edu>  
**Subject:** Covid testing swabs and medium shipment

Hi Lisa,

Our six-piece shipment fedex tracking number (b)(4) has been waiting for FDA approval and release in Memphis Tn. Since Wednesday. My understanding is that FDA has selected this shipment for physical inspection. There is no required timeframe for them to complete this inspection. It cannot be released until FDA inspection is complete. The FDA Memphis office number is (901) 333-3520.

Please let me know if you have questions  
Karyn

Karyn B. Rae, MBA  
Chief, Payor Relations and Reimbursement  
MUSC Health  
261 Calhoun Street, Ste 100  
Charleston, SC 29425  
Phone: (843) 876-1343  
Fax : (843) 876-1347



Changing What's Possible

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---

**Sent:** 4/14/2020 8:54:18 AM  
**To:** Asuka, Brandon T [Brandon.T.Asuka@hawaii.gov]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**BCC:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** RE: Hawaii Inquiry: FDA Approval (b)(4)

Aloha Brandon,

Thank you for your email regarding the (b)(4) FDA appreciates that you may be receiving many inquiries from medical product developers regarding the status of their submissions for an emergency use authorization (EUA) or approval of products intended to diagnose, treat, or prevent COVID-19. FDA recognizes the urgent nature of these submissions and is reviewing them as quickly as possible, although turnaround times can vary based on the information provided by the applicant. When questions arise or additional information is needed FDA works directly with the developer to keep the review moving. FDA prioritizes those submissions that, based on the information provided, may offer the most impact for the response.

Consistent with our legal and regulatory obligations, and to avoid even the appearance of impropriety during this critical period of product development, the agency is unable to provide status checks or updates on pending applications for anyone other than product sponsors. (In fact, unless a company has made its submission public, FDA cannot even confirm that it has been received, except to the sponsor.) Additionally, this preserves the time of the experts within the review divisions so they can complete reviews and engage with the sponsors more quickly. We thank you for your understanding and commitment to ensuring that FDA review remains the world's gold standard and maintains the highest level of integrity.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Tuesday, April 14, 2020 8:08 AM  
**To:** Asuka, Brandon T <Brandon.T.Asuka@hawaii.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Subject:** Hawaii Inquiry: FDA Approval (b)(4)

Aloha, Brandon- I hope you are doing well. I am copying my colleague, Erica White, who can assist you with this request.

Best,  
Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Christopher.Campbell@fda.hhs.gov



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**From:** Asuka, Brandon T <Brandon.T.Asuka@hawaii.gov>  
**Sent:** Monday, April 13, 2020 5:40 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FDA Approval (b)(4)

Aloha Chris,

Hoping you can assist with another opportunity in Hawaii. (b)(4)

(b)(4)

Mahalo,

Brandon T. Asuka  
Senior Special Assistant  
Office of the Governor, State of Hawaii  
Phone (Office): (808) 586-0034  
Phone (Direct): (b)(6)  
Phone (Mobile): (b)(6)  
<http://governor.hawaii.gov>

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/15/2020 8:36:00 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 14, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken yesterday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA and Federal Trade Commission (FTC) issued warning letters to three sellers of fraudulent COVID-19 products, as part of the agency's effort to protect both people and pets. With these warning letters, the FDA is

exercising its authority to protect consumers from companies selling unapproved products with false or misleading claims during the COVID-19 pandemic. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider:

- The first seller warned, Herbs of Kedem, sells unapproved and misbranded herbal products for the prevention and treatment of COVID-19.
- The second seller warned, the GBS dba Alpha Arogya India Pvt Ltd, offers unapproved and misbranded ayurvedic products including "Alpha 11" and "Alpha 21" for sale in the U.S. with misleading claims about the prevention or treatment of COVID-19.
- The third seller warned, Gaia Arise Farms Apothecary, offers unapproved and misbranded products including "True Viral Defense" also referred to as "Viral Defense Tincture." The company makes misleading claims the products are safe and/or effective for the treatment or prevention of COVID-19 in people.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 300 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, 34 emergency use authorizations have been issued for diagnostic tests.
  - The FDA has been notified that more than 180 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date, including updated FAQs regarding at-home testing:
    - At this time, the FDA has not authorized any COVID-19 test for at-home testing, including self-collection of a specimen with or without the use of telemedicine.
    - The FDA is supportive of at-home testing for COVID-19, provided there is data and science to support consumer safety and test accuracy. We are actively working with developers toward the goal of authorizing EUAs for home use tests once appropriate validation has been completed. Home collection raises several issues of importance, including whether the lay user can safely and properly collect the specimen, whether the components of the specimen transport media are safe for use in the home environment (since some may be toxic), proper shipment, and adequate stability of the specimen given the time lapse between collection and testing and the potential impact of shipping conditions (such as, if the specimen sits in a hot truck). A physician watching the collection by way of telemedicine may address the issue of proper specimen collection (if the self-collection method does not raise safety concerns) but it does not address the other issues, and specimen stability and shipping conditions are still of concern.

#### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 4/15/2020 9:43:54 AM  
**To:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**CC:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** RE: URGENT, PLEASE READ: FW: Signature on Response to State Rep. Allen re: Sterigenics

That sounds like a plan.

---

**From:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Sent:** Wednesday, April 15, 2020 9:41 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: URGENT, PLEASE READ: FW: Signature on Response to State Rep. Allen re: Sterigenics

Okay,

I will check back on this around noon to give everyone time to look.

Akeisha

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 15, 2020 9:40 AM  
**To:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** RE: URGENT, PLEASE READ: FW: Signature on Response to State Rep. Allen re: Sterigenics

Hi Akeisha,

My understanding is that Jeff is going to sign it. I am not sure if Erika or Nick want to take another look at it. I would wait to see if they weigh in on it, or if Karen answers, which I doubt.

Erica

---

**From:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Sent:** Wednesday, April 15, 2020 9:27 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
**Subject:** RE: URGENT, PLEASE READ: FW: Signature on Response to State Rep. Allen re: Sterigenics

Is this ready to be finalized for signature, or are we waiting for Karen's input? Also, have we decided if Dr. Shuren will be signee or the Commissioner?

-Akeisha

---

**From:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Sent:** Wednesday, April 15, 2020 9:10 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell,



Christopher <Christopher.Campbell@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; OCCRequests-COVID19 <(b)(6)>

**Subject:** RE: URGENT, PLEASE READ: FW: Signature on Response to State Rep. Allen re: Sterigenics

Hi Karen,

I added a couple minor edits to the response. Thanks and let me know if you have any questions.

Best,  
Jaycie

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Sent:** Wednesday, April 15, 2020 9:01 AM

**To:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

**Cc:** White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; OCCRequests-COVID19 <(b)(6)>

**Subject:** URGENT, PLEASE READ: FW: Signature on Response to State Rep. Allen re: Sterigenics

Hi Jaycie-

We put this in final type last night and it just occurred to me that Erika made some minor edits that I thought you should see just because of the different moving parts here. I doubt there will be any concerns but just in case running by you. I am out today, only available by phone. Please reply all so my colleagues in IGA can handle any changes. Thank you

---

**From:** Meister, Karen G

**Sent:** Tuesday, April 14, 2020 6:15 PM

**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>

**Subject:** Re: Signature on Response to State Rep. Allen re: Sterigenics

Hi Jennifer-

(b)(5) Please let us know if that works. Akeisha will be finalizing so needs to know whose signature. (b)(6) I'm hoping Erica White can handle, otherwise, Chris will step in.

(b)(6) Thank you!

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office*

(b)(6) work cell)  
personal cell- I will call you back on work phone)

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/20/2020 8:02:31 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 17, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken Friday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration Friday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The National Institutes of Health (NIH) and the Foundation for the NIH announced a public-private partnership with the FDA and others to speed the development of COVID-19 vaccine and treatment options. The Accelerating

COVID-19 Therapeutic Interventions and Vaccines (ACTIV) partnership also includes the U.S. Centers for Disease Control and Prevention, the European Medicines Agency, the U.S. Department of Health and Human Services Office of the Assistant Secretary for Preparedness and Response, as well as more than a dozen biopharmaceutical companies. The ACTIV partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics.

- Friday, a federal court has entered an emergency temporary restraining order and a preliminary injunction against the Genesis II Church of Health and Healing (Genesis) and four individuals associated with the entity requiring them to immediately stop distributing its "Miracle Mineral Solution" (MMS), an unproven and potentially harmful treatment offered for sale to treat Coronavirus, which includes Coronavirus Disease 2019 (COVID-19) and many other diseases. The FDA, jointly with the Federal Trade Commission (FTC), previously issued a warning letter to Genesis and the FDA has warned consumers numerous times over the past decade not to purchase or drink chlorine dioxide products such as MMS sold as medical treatments. The FDA and FTC requested that the company respond within 48 hours describing the specific steps it has taken to correct the violations. In response to the warning letter, the defendants made clear that they had no intention of taking corrective action and would continue to sell MMS in violation of the law.
- The FDA and FTC issued a warning letter to a seller of fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The seller warned, Nova Botanix LTD DBA CanaBD, sells unapproved and misbranded cannabidiol (CBD) products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
- Thursday, FDA announced a further expansion of COVID-19 testing options through the recognition that spun synthetic swabs – with a design similar to Q-tips – could be used to test patients by collecting a sample from the front of the nose. As part of this effort, U.S. Cotton, the largest manufacturer of cotton swabs and a subsidiary of Parkdale-Mills, developed a polyester-based Q-tip-type swab that is fully synthetic for compatibility with COVID-19 testing. Harnessing its large-scale U.S.-based manufacturing capabilities, U.S. Cotton plans to produce these new polyester swabs in large quantities to help meet the needs for coronavirus diagnostic testing.
- The FDA issued a new emergency use authorization (EUA) for Extracorporeal Blood Purification (EBP) to ExThera Medical Corporation for emergency use of the Seraph 100 Microbind Affinity Blood Filter device to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit with confirmed or imminent respiratory failure to reduce pathogens and inflammatory mediators from the bloodstream. The Seraph 100 Microbind Affinity Blood Filter device is an extracorporeal broad-spectrum sorbent hemoperfusion device that is designed to reduce bacteria, viruses, toxins, cytokines and other inflammatory mediators from whole blood. The Seraph 100 Microbind Affinity Blood Filter device is designed to share a form factor very similar to other blood filters, such as hemodialyzers or hemoperfusion filters, and therefore is compatible with hemodialysis systems that use industry standard bloodline connectors for ease of operation, training, and utility.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 320 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, the FDA has issued 39 individual emergency use authorizations for test kit manufacturers and laboratories. In addition, 16 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 190 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

#### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 4/20/2020 8:04:50 AM  
**To:** Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gome]  
**Subject:** RE: connecting on stakeholder

Good morning Rachel,

I saw the email on

---

**From:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Sent:** Saturday, April 18, 2020 6:35 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Re: connecting on stakeholder

Good afternoon Karen

I'm unable send the emails. After emailing thousands of recipients (~19,000) the covid resources pdf , my outlook email on my laptop cannot send any more emails due to the error "The message can't be submitted because the sender's submission quota was exceeded."

I have a Tier II ERIC ticket and they estimate a Monday call back to resolve the issue.

**Rachel Gomez 郭瑞秋**

Intergovernmental Affairs (IGA) - Detailee

Cell: (b)(6)

Assistant Country Director | U.S. Embassy, P.R. of China  
Office of Global Policy and Strategy - Office of Global Operations  
U.S. Food and Drug Administration

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---

**From:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Date:** April 17, 2020 at 8:35:56 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: connecting on stakeholder

Erica

Who would you send to? These list have lots of undeliverable email addresses

Thanks

Rachel

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** April 17, 2020 at 5:25:52 PM EDT  
**To:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>, Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>  
**Subject:** FW: connecting on stakeholder

Hi Rachel-

Attached are the lists to whom the outreach described below should be sent once you get the go ahead from Dayle. Thank you for doing this!

Have a good weekend. Karen

---

**From:** Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>  
**Sent:** Thursday, April 16, 2020 5:03 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: connecting on stakeholder  
**Importance:** High

Hi there. So, I'm on the hook for compiling a good outreach list for the groups below regarding FDA's approved Serology tests. CDRH is going to put out a letter to HC Providers and a Fact sheet late tomorrow or Saturday, followed by a press statement, basically pointing to the 3 EUAs that we've approved and the data we have in house for accuracy. OC wants this message out broadly. Can you help distribute to your folks, or alternatively if you want to just send me your list I can just include in the outreach when send ours? Also, below is just a first cut of who I thought should get this message. If you have others you want to include, please do.

- o Health Professional Organizations (doctors, hospitals, nurses, medical specialty groups)
- o Public Health Organizations (APHA, Clinical Research Professionals)
- o Laboratories- (ACLA, AAMC, APHL)
- o Trade Associations (biomedical industry, device, food, drug stores)
- o Academia/Think Tanks (Pew, CATO, Public Health Research organizations, Academic Medical Centers)
- o Consumer Organizations (National Consumers League, etc.)
- o State/Local Government/Tribal (State Departments of Health, ASTHO, Counties, Cities)
- o Federal Partners (VA, DOD, IHS, CMS)
- o Insurance Industry (AHIP, and large payors)

**Dayle Lewis Cristinzio**

Director, Stakeholder Engagement

Office of External Affairs

U.S. Food and Drug Administration

(t) 301.796.8898 | (b)(6)

dayle.cristinzio@fda.hhs.gov



---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

**Sent:** Thursday, April 16, 2020 4:51 PM

**To:** Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>

**Subject:** connecting on stakeholder

Can you two huddle on the full list?

- NOTE: stakeholder outreach list in development, but will include the following categories:

**Laura Caliguiri**

*Associate Commissioner for External Affairs*

Office of External Affairs  
U.S. Food and Drug Administration  
Tel: 301 796-8546  
Laura.Caliguiri@fda.hhs.gov



---

**Sent:** 4/20/2020 8:24:31 AM  
**To:** Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gomez]  
**Subject:** RE: connecting on stakeholder

It looks like the most important ones made it out, which are the ones to the states

---

**From:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Sent:** Monday, April 20, 2020 8:19 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: connecting on stakeholder

Hi Erica

Only some went out before I hit the quota. Honestly, I have not determined which ones went through And which ones didn't.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Date:** April 20, 2020 at 8:08:20 AM EDT  
**To:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Subject:** RE: connecting on stakeholder

Good morning Rachel,

Sorry about the drama surrounding all of this over the weekend. Looks like you were able to send it out, let me know if that wasn't the case.

Erica

---

**From:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>  
**Sent:** Saturday, April 18, 2020 6:35 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Re: connecting on stakeholder

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Rachel Gomez 郭瑞秋  
Intergovernmental Affairs (IGA) - Detailee  
Cell: (b)(6)



Assistant Country Director | U.S. Embassy, P.R. of China  
Office of Global Policy and Strategy - Office of Global Operations  
U.S. Food and Drug Administration

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**From:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>

**Date:** April 17, 2020 at 8:35:56 PM EDT

**To:** White, Erica <Erica.White@fda.hhs.gov>

**Subject:** FW: connecting on stakeholder

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Who would you send to? These list have lots of undeliverable email addresses

Thanks

Rachel

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Date:** April 17, 2020 at 5:25:52 PM EDT

**To:** Gomez, Rachel A. <Rachel.Gomez@fda.hhs.gov>

**Cc:** White, Erica <Erica.White@fda.hhs.gov>, Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>

**Subject:** FW: connecting on stakeholder

Hi Rachel-

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Have a good weekend. Karen

---

**From:** Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>

**Sent:** Thursday, April 16, 2020 5:03 PM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>

**Subject:** FW: connecting on stakeholder

**Importance:** High

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- Public Health Organizations (APHA, Clinical Research Professionals)
- Laboratories- (ACLA, AAMC, APHL)
- Trade Associations (biomedical industry, device, food, drug stores)
- Academia/Think Tanks (Pew, CATO, Public Health Research organizations, Academic Medical Centers)
- Consumer Organizations (National Consumers League, etc.)
- State/Local Government/Tribal (State Departments of Health, ASTHO, Counties, Cities)
- Federal Partners (VA, DOD, IHS, CMS)
- Insurance Industry (AHIP, and large payors)

**Dayle Lewis Cristinzio**

Director, Stakeholder Engagement

Office of External Affairs

U.S. Food and Drug Administration

(t) 301.796.8898 | (m) (b)(6)

dayle.cristinzio@fda.hhs.gov



---

**From:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

**Sent:** Thursday, April 16, 2020 4:51 PM

**To:** Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Jungman, Elizabeth <Elizabeth.Jungman@fda.hhs.gov>

**Subject:** connecting on stakeholder

Can you two huddle on the full list?

- NOTE: stakeholder outreach list in development, but will include the following categories:

Laura Caliguiri

*Associate Commissioner for External Affairs*

Office of External Affairs

U.S. Food and Drug Administration

Tel: 301 796-8546

Laura.Caliguiri@fda.hhs.gov



---

**Sent:** 4/20/2020 2:14:12 PM  
**Subject:** FW: FDA EUA for face masks

Good afternoon Valerie,

Thank you for your email below regarding the FDA EUA for face masks. On April 18, FDA issued a letter of authorization. Face masks are authorized under this EUA when they are intended for use by members of the general public, including HCPs in healthcare settings as PPE, to cover their noses and mouths, in accordance with CDC recommendations, to prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);
2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection, and includes recommendations that would reduce the risk of such use; for example, the labeling might include recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; or as an alternative example, recommendations for use only by the general public; and
3. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling should not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction, nor should it be used for particulate filtration

Manufacturers of face masks that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policyframework/emergency-use-authorization>, serves as face mask manufacturers' notification of authorization.

---

**From:** Lott, Valerie <valerie.lott@dhhs.nc.gov>  
**Sent:** Monday, April 20, 2020 11:30 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FDA EUA for face masks

Hi Karen and Erica,

Happy Monday! The FDA put [out guidance](#) on face mask. My question is in reference to the statement below.

***The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection, and includes recommendations that would reduce the risk of such use; for example, the labeling might include recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; or as an alternative example, recommendations for use only by the general public; a***

I have bolded the statements I have a question about. We are looking at using this EUA to allow some imported procedural masks or masks that are manufactured from non FDA registered companies that meet the EUA

guidelines. My question is under this EUA can we do that? The information above say that the mask can't claim to be used for liquid barrier protection, but then gives an example about significant exposure to liquid. A procedural mask would be a level I mask according to ASTM.

Please advise.

Valerie Lott, MPH, REHS  
Industrial Hygiene Consultant Supervisor  
Division of Public Health, Epidemiology Section  
North Carolina Preparedness and Response  
225 N. McDowell St.  
1902 MSC  
Raleigh, NC 27699-1900  
919-546-1823-office

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919-715-2246-fax

**888-820-0520 (PHP&R 24/7 On-call)**

Valerie.Lott@dhhs.nc.gov



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**Sent:** 4/21/2020 9:30:51 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: FYI, preparing to issue, LabCorp at home test collection

I will as soon as I see that it's public on our web page.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 21, 2020 9:30 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: FYI, preparing to issue, LabCorp at home test collection  
**Importance:** High

Outreach?

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Tuesday, April 21, 2020 8:00 AM  
**To:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Price, William <William.Price@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: FYI, preparing to issue, LabCorp at home test collection  
**Importance:** High

Good morning all – please distribute this widely to the Hill and to any state and local government contacts who will be interested. Please also provide the information below from yesterday's daily round up at the beginning of your email to remind folks about all the developers and others we are working with to rapidly increase testing capacity in the U.S.

Will be happy to address any questions folks have.

Best,

Jennifer

Diagnostics update to date:

(b)(5)

**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



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

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**From:** Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>

**Sent:** Tuesday, April 21, 2020 7:53 AM

**To:** OMA-Notifications <(b)(6)>

**Cc:** 2019-nCoV FDA IMG JIC <(b)(6)>; OC OEA OMA-Press <(b)(6)>  
<(b)(6)>

**Subject:** FYI, preparing to issue, LabCorp at home test collection

Hi—we'll issue this now.

**Stephanie Caccamo**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.348.1556  
Cell: (b)(6)  
stephanie.caccamo@fda.hhs.gov

---

**From:** Caccamo, Stephanie

**Sent:** Monday, April 20, 2020 10:09 PM

**To:** OMA-Notifications <(b)(6)>

**Cc:** 2019-nCoV FDA IMG JIC <(b)(6)>; OC OEA OMA-Press <(b)(6)>  
<(b)(6)>

**Subject:** FYI, preparing to issue, LabCorp at home test collection

FYI, OMA will issue this shortly. A press release on an EUA for the first at home collection test. Thanks!

**Stephanie Caccamo**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.348.1556  
Cell: (b)(6)  
stephanie.caccamo@fda.hhs.gov

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**Sent:** 4/21/2020 10:44:03 AM

**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; kalanikaneko@gmail.com; emais.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]

**Subject:** FDA Authorizes First Test for Patient At-Home Sample Collection

Good morning,

The FDA's Intergovernmental Affairs (IGA) team would like to bring your attention that the Agency has authorized the first diagnostic test with a home collection option for COVID-19. Specifically, the FDA re-issued the emergency use authorization (EUA) for the Laboratory Corporation of America (LabCorp) COVID-19 RT-PCR Test to permit testing of samples self-collected by patients at home using LabCorp's Pixel by LabCorp COVID-19 Test home collection kit.

The entire announcement can be found below and at this link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection>

If you have any questions please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



## **FDA NEWS RELEASE**

### **Coronavirus (COVID-19) Update: FDA Authorizes First Test for Patient At-Home Sample Collection**

The U.S. Food and Drug Administration authorized the first diagnostic test with a home collection option for COVID-19. Specifically, the FDA re-issued the emergency use authorization (EUA) for the Laboratory Corporation of America (LabCorp) COVID-19 RT-PCR Test to permit testing of samples self-collected by patients at home using LabCorp's Pixel by LabCorp COVID-19 Test home collection kit.

“Throughout this pandemic we have been facilitating test development to ensure patients access to accurate diagnostics, which includes supporting the development of reliable and accurate at-home sample collection options,” said FDA Commissioner Stephen M. Hahn, M.D. “The FDA’s around-the-clock work since this outbreak began has resulted in the authorization of more than 50 diagnostic tests and engagement with over 350 test developers. Specifically, for tests that include home sample collection, we worked with LabCorp to ensure the data demonstrated from at-home patient sample collection is as safe and accurate as sample collection at a doctor’s office, hospital or other testing site. With this action, there is now a convenient and reliable option for patient sample collection from the comfort and safety of their home.”

This reissued EUA for LabCorp’s molecular test permits testing of a sample collected from the patient’s nose using a designated self-collection kit that contains nasal swabs and saline. Once patients self-swab to collect their nasal sample, they mail their sample, in an insulated package, to a LabCorp lab for testing. LabCorp intends to make the Pixel by LabCorp COVID-19 Test home collection kits available to consumers in most states, with a doctor’s order, in the coming weeks.

The LabCorp home self-collection kit includes a specific Q-tip-style cotton swab for patients to use to collect their sample. Due to concerns with sterility and cross-reactivity due to inherent genetic material in cotton swabs, other cotton swabs should not be used with this test at the present time. The FDA continues to work with test developers to determine whether or not Q-tip-style cotton swab can be used safely and effectively with other tests.

This authorization only applies to the LabCorp COVID-19 RT-PCR Test for at-home collection of nasal swab specimens using the Pixel by LabCorp COVID-19 home collection kit. It is important to note that this is not a general authorization for at-home collection of patient samples using other collection swabs, media, or tests, or for tests fully conducted at home.



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**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Letter from Governor Hogan to President Trump (COVID-19 Testing)  
**Attachments:** Letter to President from Governor Hogan 4.21.20.pdf

Good afternoon,

IGA received this email and attached letter from Gov. Hogan.

**From:** Ariel Judah -GOV- <ariel.judah@maryland.gov>  
**Sent:** Tuesday, April 21, 2020 3:57 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; IGA <IGA@fda.hhs.gov>  
**Cc:** Tiffany Waddell <tiffany.waddell@maryland.gov>; Madeline Marks -GOV- <madeline.marks@maryland.gov>  
**Subject:** Letter from Governor Hogan to President Trump (COVID-19 Testing)

Good afternoon Erica,

Dr. Hahn is copied on the attached letter to President Trump from Governor Hogan regarding access to federal labs for COVID-19 testing.

Please let me know if you have any questions.

Best Regards,  
Ariel

**Ariel Judah**  
Deputy Director of Federal Relations  
Office of the Governor  
444 N. Capitol St. NW, Suite 311  
Washington, DC 20001  
ariel.judah@maryland.gov  
(202) 624-1472 (O)

(b)(6)  
Website | Facebook | Twitter

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**Sent:** 4/24/2020 10:45:42 AM  
**To:** OC OCC Biologics Team Assignments [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1802635c07ae46ca83b2021f0d85cc88-OCOCBiolog]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)  
**Attachments:** COB Tracking C20-212 - Sen Weiner- Convalescent plasma -MSM donors CBER final.docx

Good morning OC,

Attached is the CBER cleared draft response to a letter from California State Sen Weiner regarding LGBTQ blood donations. The letter is based on an already cleared letter, however with additional language that needs OCC clearance. CBER has highlighted the portion that needs to be OCC cleared.

Please review and clear by

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 24, 2020 10:40 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Good morning Erica.

I have attached CBER's response to the inquiry from Senator Weiner. Please note that this response was drafted using language from a response to inquiry from Rep. Quigley that was reviewed by OCC. The response to the inquiry from Senator Weiner was tailored to address the issues identified in his inquiry and has some new language. I have highlighted the section that OCC needs to review.

Thank you for your patience and please let us know if you have any questions.

Best regards,  
Bharti.

*Bharti Patel  
Consumer Safety Officer  
Congressional and Oversight Branch  
Division of Disclosure and Oversight Management  
CBER/FDA*

240-402-8138

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:26 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

That works. Thanks for letting me know.

Erica

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:23 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

I am hoping to get it to you in next few days.

Thanks,  
Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:21 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks for the update. Do you have an estimated time when it might be done, so I can let FDA Exec Sec know?

Erica

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:18 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

The response is still under review within CBER. Can we please get an extension?

Thanks,  
Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:11 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks Bharti,

That should be fine. Please keep us posted.

Erica

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:10 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

We will try but may need an extension due to other priorities related to COVID-19.

Thanks,  
Bharti

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:03 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Bharti,

If possible, can we receive the cleared final version by COB Wednesday?

Erica

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 1:58 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Subject:** FW: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica-

Can you please respond to Bharti? Thanks

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 1:55 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Karen.

Hope all is well. You may be aware of the attached inquiry. We are working on it but we do not know what the due date is. Can you please let us know?

Thanks,  
Bharti

---

**Sent:** 4/27/2020 7:27:59 AM  
**To:** Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz\_bohn]; Patel, Bharti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=933ead78c9584fc6bb322f739bdaf5bc-Patelb]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; OC OCOD Contacts [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=502e664f195a4e55ad34e3345edc2005-OC OCOD Con]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Good morning Susan,

Yes, IGA does routinely send items to OP for review. Since

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Friday, April 24, 2020 6:35 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica,

The responses to letters regarding MSM that come through FDA Exec Sec are sent to both OCC and OP for clearance. Bharti mentioned that OCC needed to review the highlighted section because it was not previously cleared. Does IGA routinely send responses through OP?

Thanks,  
Susan

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**From:** Patel, Bharti  
**Sent:** Friday, April 24, 2020 10:40 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Good morning Erica.

I have attached CBER's response to the inquiry from Senator Weiner. Please note that this response was drafted using language from a response to inquiry from Rep. Quigley that was reviewed by OCC. The response to the inquiry from Senator Weiner was tailored to address the issues identified in his inquiry and has some new language. I have highlighted the section that OCC needs to review.

Thank you for your patience and please let us know if you have any questions.

Best regards,  
Bharti.

Bharti Patel  
Consumer Safety Officer  
Congressional and Oversight Branch  
Division of Disclosure and Oversight Management  
CBER/FDA

240-402-8138

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**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

That works. Thanks for letting me know.

Erica

---

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**Sent:** Wednesday, April 22, 2020 2:23 PM  
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**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

I am hoping to get it to you in next few days.

Thanks,  
Bharti

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**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks for the update. Do you have an estimated time when it might be done, so I can let FDA Exec Sec know?

Erica

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**Sent:** Wednesday, April 22, 2020 2:18 PM  
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**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

The response is still under review within CBER. Can we please get an extension?

Thanks,  
Bharti

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**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks Bharti,

That should be fine. Please keep us posted.

Erica

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**Sent:** Friday, April 17, 2020 2:10 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

We will try but may need an extension due to other priorities related to COVID-19.

Thanks,  
Bharti

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**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Bharti,

If possible, can we receive the cleared final version by COB Wednesday?

Erica

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**Sent:** Friday, April 17, 2020 1:58 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Subject:** FW: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica-

Can you please respond to Bharti? Thanks

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 1:55 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** OC OCOD Contacts [REDACTED] (b)(6)  
**Subject:** inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Karen.

Hope all is well. You may be aware of the attached inquiry. We are working on it but we do not know what the due date is. Can you please let us know?

Thanks,  
Bharti



---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/27/2020 7:34:00 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@mshd.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@palauhealth.org; emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymerly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for April 24, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken Friday by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration Friday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA issued an immediately in effect guidance, Enforcement Policy for Remote Digital Pathology Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency, to help expand the availability of devices for

remote reviewing and reporting of scanned digital images of pathology slides during this public health emergency. Increased availability of these devices may help to facilitate continuity of patient care by preventing disruptions to critical pathology services rendered by clinical laboratories, hospitals, and other healthcare facilities, and reduce healthcare personnel contact and risk of exposure to SARS-CoV-2.

- The FDA issued a Drug Safety Communication regarding known side effects of hydroxychloroquine and chloroquine, including serious and potentially life-threatening heart rhythm problems, that have been reported with their use for the treatment or prevention of COVID-19, for which they are not approved by the FDA. These risks, which are in the drug labels for their approved uses, may be mitigated when health care professionals closely screen and supervise these patients such as in a hospital setting or a clinical trial, as indicated in the Emergency Use Authorization (EUA) for these drugs to treat COVID-19.

- The FDA and Federal Trade Commission issued a warning letter to a seller of fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The seller warned, Prefense LLC, offers unapproved and misbranded hand sanitizer products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.

- Diagnostics update to date:

- During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.

- To date, the FDA has issued 44 individual emergency use authorizations for test kit manufacturers and laboratories. In addition, 19 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).

- The FDA has been notified that more than 225 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.

- The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

#### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 4/28/2020 7:53:44 AM  
**Subject:** FW: EUA Status - COVID-19 Serological test

Good morning,

Wanted to make sure this was okay to send back to Garrett,

Good morning Garrett,

Thank you for your email below requesting an update on the status of an emergency use authorization (EUA) application for COVID-19 serological testing which was submitted and/or any general update on the timeline or process for these approvals. FDA appreciates that you may be receiving many inquiries from medical product developers regarding the status of their submissions for an EUA or approval of products intended to diagnose, treat, or prevent COVID-19. FDA recognizes the urgent nature of these submissions and is reviewing them as quickly as possible, although turnaround times can vary based on the information provided by the applicant. When questions arise or additional information is needed FDA works directly with the developer to keep the review moving. FDA prioritizes those submissions that, based on the information provided, may offer the most impact for the response.

Consistent with our legal and regulatory obligations, and to avoid even the appearance of impropriety during this critical period of product development, the agency is unable to provide status checks or updates on pending applications for anyone other than product sponsors. (In fact, unless a company has made its submission public, FDA cannot even confirm that it has been received, except to the sponsor.) Additionally, this preserves the time of the experts within the review divisions so they can complete reviews and engage with the sponsors more quickly. We thank you for your understanding and commitment to ensuring that FDA review remains the world's gold standard and maintains the highest level of integrity.

If you, or the company, need additional information, including about tests being offered prior to or without an EUA under the policies in the *Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency*, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2.

Hopefully this is helpful. If you have any further questions, please feel free to reach out.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Garrett Wheat <GWheat@senate.michigan.gov>  
**Sent:** Monday, April 27, 2020 5:08 PM  
**To:** IGA <IGA@fda.hhs.gov>

Cc: Ruth Johnson <RJohnson@senate.michigan.gov>

Subject: EUA Status - COVID-19 Serological test

Hello,

I am writing to see if we can please get an update on the status of an EUA application for COVID-19 serological testing which was submitted and/or any general update on the timeline or process for these approvals.

I was able to speak with CDRH staff directly last month and directed this company to the covid19dx@fda.hhs.gov email and they were able to successfully submit their application for an EUA for serological testing on (b)(4) but have not received any update since. Their application information is below, we would appreciate any update on the status:

We filed for an EUA/Notify on: (b)(4)

Our PIN# is: (b)(4)

Our PCN# is: (b)(4)

Our Owner Operator # is: (b)(4)

Our US Agent Receipt Code is: (b)(4)

Product Code is: (b)(4)

Please let me know if you have any questions.

Thank you,

-Garrett

Garrett Wheat

Chief of Staff

State Senator Ruth Johnson

Michigan, 14<sup>th</sup> District

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**Sent:** 4/28/2020 9:36:10 AM  
**Subject:** FW: EUA Status - COVID-19 Serological test

Good morning Jennifer,

Before I send this email back to the state I wanted to check, for my own education, whether the three week timeframe for approval is normal

Good morning Garrett,

Thank you for your email below requesting an update on the status of an emergency use authorization (EUA) application for COVID-19 serological testing which was submitted and/or any general update on the timeline or process for these approvals. FDA appreciates that you may be receiving many inquiries from medical product developers regarding the status of their submissions for an EUA or approval of products intended to diagnose, treat, or prevent COVID-19. FDA recognizes the urgent nature of these submissions and is reviewing them as quickly as possible, although turnaround times can vary based on the information provided by the applicant. When questions arise or additional information is needed FDA works directly with the developer to keep the review moving. FDA prioritizes those submissions that, based on the information provided, may offer the most impact for the response.

Consistent with our legal and regulatory obligations, and to avoid even the appearance of impropriety during this critical period of product development, the agency is unable to provide status checks or updates on pending applications for anyone other than product sponsors. (In fact, unless a company has made its submission public, FDA cannot even confirm that it has been received, except to the sponsor.) Additionally, this preserves the time of the experts within the review divisions so they can complete reviews and engage with the sponsors more quickly. We thank you for your understanding and commitment to ensuring that FDA review remains the world's gold standard and maintains the highest level of integrity.

If you, or the company, need additional information, including about tests being offered prior to or without an EUA under the policies in the *Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency*, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2.

Hopefully this is helpful. If you have any further questions, please feel free to reach out.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Garrett Wheat <GWheat@senate.michigan.gov>  
**Sent:** Monday, April 27, 2020 5:08 PM

To: IGA <IGA@fda.hhs.gov>  
Cc: Ruth Johnson <RJohnson@senate.michigan.gov>  
Subject: EUA Status - COVID-19 Serological test

Hello,

I am writing to see if we can please get an update on the status of an EUA application for COVID-19 serological testing which was submitted and/or any general update on the timeline or process for these approvals.

I was able to speak with CDRH staff directly last month and directed this company to the covid19dx@fda.hhs.gov email and they were able to successfully submit their application for an EUA for serological testing on (b)(4) but have not received any update since. Their application information is below, we would appreciate any update on the status:

We filed for an EUA/Notify on (b)(4)  
Our PIN# is (b)(4)  
Our PCN# is (b)(4)  
Our Owner Operator # is (b)(4)  
Our US Agent Receipt Code is (b)(4)  
Product Code is (b)(4)

Please let me know if you have any questions.

Thank you,  
-Garrett

Garrett Wheat  
Chief of Staff  
State Senator Ruth Johnson  
Michigan, 14<sup>th</sup> District

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**Sent:** 4/28/2020 1:47:40 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** RE: Coronavirus (COVID-19) Update: Daily Roundup for April 27, 2020

Governor's Fed Reps, Health Depts, ASTHO, NACCHO, and NGA.

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 1:47 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup for April 27, 2020

I need to let HHS know to whom we send this....can you confirm?

Gov: state reps? Chiefs of staff?  
State Health Depts?

Thanks!

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**From:** IGA <IGA@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 7:39 AM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 27, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA issued a statement, "Coronavirus (COVID-19) Update: FDA Continues to Ensure Availability of Alcohol-Based Hand Sanitizer During the COVID-19 Pandemic, Address Safety Concerns," to discuss the Agency's efforts to increase availability of alcohol-based hand sanitizer and the importance of making hand sanitizer unpalatable to people, including children, through the use of denatured alcohol. Calls to the National Poison Data System last month related to hand sanitizer increased by 79 percent compared to March 2019, with the majority of these calls accounting for unintentional exposures in children 5 years of age and younger. The statement also warns consumers about hand sanitizer sold with fraudulent claims.
- The FDA developed a fact sheet in collaboration with the Centers for Disease Control and Prevention (CDC) to help answer questions from the food and agriculture sector about what respirators, disposable facemasks, such as surgical or medical masks, or cloth face coverings are most appropriate for various settings.
- The FDA also developed a fact sheet, What to Do If You Have COVID-19 Confirmed Positive or Exposed Workers in your Food Production, Storage, or Distribution Operations Regulated by FDA, derived from CDC recommendations. This fact sheet summarizes key steps that employers and workers can take to help stay open, prevent and slow the spread of COVID-19, and support continuity of essential operations if workers are diagnosed with or exposed to COVID-19, or show symptoms associated with COVID-19.
- After receiving questions and concerns about the Emergency Use Authorization (EUA) for face masks posted on April 18, 2020, the FDA updated and re-issued the EUA. In doing so, the FDA clarified that face masks, including cloth

face coverings, that are authorized by the EUA are only authorized for use by the general public and health care personnel as source control. These face masks are not authorized to be personal protective equipment, meaning they are not a substitute for filtering face piece respirators or surgical face masks. The FDA also posted FAQs on the [Emergency Use Authorization for Face Masks \(Non-Surgical\)](#).

- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, the FDA has issued 49 individual emergency use authorizations for test kit manufacturers and laboratories. In addition, 21 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 225 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)



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**Sent:** 4/28/2020 4:27:27 PM  
**Subject:** FW: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Haley,

If possible, can we have the contact information for the Wisconsin staffer that is requesting the information? As I am sure you are aware, our staff is working tirelessly on COVID 19 related items, so carving out time would be challenging. We would like to request specific questions that may be of interest for their publication. We would also like to share the following link as it provides information on the vaccine approval process and may serve as an initial resource <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>

Please let me know if you have any questions.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 4:18 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <(b)(6)>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Subject:** FW: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,  
I hope all is well with you.

We discussed this request internally. As you know, our staff in our office of vaccines is working non-stop on applications for vaccines to fight COVID-19.

Would you please ask Ms. Nicolson for contact information for the Wisconsin State legislative staffer for so you can request specific questions that are of interest for their publication? We will use those questions to decide if it will be more efficient to have a brief (15 min call) at a pre-arranged time or to respond in writing. We don't have any background but if you feel it is appropriate, you can provide the following link on the vaccine approval process as an initial resource <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>

Thanks,

Susan

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, April 27, 2020 4:50 PM  
**To:** CBER Exec. Sec. <cber\_execsec@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Good afternoon,

IGA received a request from the National Conference of State Legislatures (NCSL) on behalf of a state legislative staffer to speak with someone at FDA about the biologic vaccine licensure process. The person is working on a publication on vaccine development and immunization for the Wisconsin Legislature. Any assistance you can provide with getting a point of contact for the Wisconsin State legislative staffer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



Erica

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**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>  
**Sent:** Monday, April 27, 2020 8:43 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** Request from Legislative Staff

Good Morning Chris,

We got a request from legislative staff to speak with someone at FDA about the biologic vaccine licensure process. He is working on a publication on vaccine development and immunization for the Wisconsin Legislature. He asked if we could speak to someone this week which I told my colleagues who got this request that might be a stretch with all that is going on. Let me know what you advise and I appreciate any resources you all can share.

Thank You!

Haley Nicholson  
National Conference of State Legislatures  
Senior Policy Director, Health & Human Services  
State-Federal Affairs  
202-624-8662 (o)



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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 4/29/2020 7:59:24 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 28, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA issued a new video resource explaining Emergency Use Authorizations (EUAs), one of several tools FDA uses to help make important medical products available quickly during public health emergencies like the COVID-19

pandemic. As the video explains, EUAs provide more timely access to drugs, diagnostic tests and/or other critical medical products that can help diagnose, treat and/or prevent COVID-19. When deciding whether to issue an EUA, the FDA evaluates the available scientific evidence very quickly and carefully balances any known and potential benefits and/or risks of these products to the public.

- The FDA and Federal Trade Commission (FTC) issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
  - The first seller warned, Hogewell Essential Oils, offers essential oils and herbal products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19.
  - The second seller warned, Santiste Labs LLC, the "Defend™ Patch," a transdermal patch containing a "composition of botanical oils," for sale in the U.S. with misleading claims that the product is safe and/or effective for the prevention or treatment of COVID-19.
- As part of its work to help protect public health, FDA updated its FAQ page with information about smoking and COVID-19. Smoking cigarettes can leave smokers more vulnerable to respiratory illnesses such as COVID-19, which is why there's never been a better time to quit smoking. FDA's Every Try Counts campaign has supportive tips and tools to help smokers get closer to quitting for good.
- The FDA posted information and resources to assist manufacturers submitting generic drug applications with bioequivalence studies that may be impacted during COVID-19.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, the FDA has issued 50 individual emergency use authorizations for test kit manufacturers and laboratories. In addition, 22 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 230 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

#### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 4/29/2020 9:04:36 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Questions from the Texas Attorney General's Office re Non-EUA serological testing  
**Attachments:** RE\_Reliant Letter of Notification part 2.pdf; RE\_Reliant Letter of Notification.pdf

I am not aware of any special precautions they should take.

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**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 11:43 PM  
**To:** Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>  
**Cc:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Re: Questions from the Texas Attorney General's Office re Non-EUA serological testing

Thank you for flagging, Rob. Adding Karen and Erica from IGA, who will likely want to be looped in on the response.

Jennifer

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**From:** Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>  
**Date:** April 28, 2020 at 11:34:35 PM EDT  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>  
**Subject:** FW: Questions from the Texas Attorney General's Office re Non-EUA serological testing  
**Importance:** High

Jennifer,

Any special precautions we need to take I discussing with the Texas Attorney General's Office?

**Robert Sauer**

Deputy Director

DPOM: Division of Program Operations and Management | OHT7: Office of In Vitro Diagnostics and Radiological Health  
CDRH | Food and Drug Administration

White Oak, Bldg. 66 Rm 3434 | 10903 New Hampshire Avenue | Silver Spring, MD 20993

Tel: 301-796-3580

Robert.A.Sauer@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=1960&S=E>.

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**From:** CDRH-EUA-Templates <(b)(6)>  
**Sent:** Tuesday, April 28, 2020 9:10 AM  
**To:** Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>  
**Cc:** CDRH-EUA-Templates <(b)(6)>  
**Subject:** FW: Questions from the Texas Attorney General's Office re Non-EUA serological testing  
**Importance:** High

Rob,

The communications between Reliant and CDRH template box and notification team are attached.

These questions will be about (b)(5)

(b)(5)

Can you contact them?

Yvonne

---

**From:** Dinunzio, Nanette <Nanette.Dinunzio@oag.texas.gov>

**Sent:** Tuesday, April 28, 2020 8:50 AM

**To:** CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>

**Cc:** Dinunzio, Nanette <Nanette.Dinunzio@oag.texas.gov>

**Subject:** Questions from the Texas Attorney General's Office re Non-EUA serological testing

**Importance:** High

Good Morning,

This email is for Yvonne, as she is the person who has been corresponding with a business here in Texas, (b)(4) regarding non-EUA serological testing it has been carrying out in Texas.

I have some questions regarding the FDA policy for this type of testing, and would appreciate the opportunity to discuss this with you. I can be reached anytime at the following number: 512.475.4654. If you reach my voicemail, please leave a message and I will call you right back.

Thank you for your assistance,

Nanette DiNunzio  
Assistant Attorney General  
Consumer Protection Division  
(512) 475-4654

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**Sent:** 4/29/2020 9:58:21 AM  
**To:** Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz\_bohn]  
**CC:** OC OCOD Contacts [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=502e664f195a4e55ad34e3345edc2005-OC OCOD Con]; Bartell, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e9ea8198fc524f22a73af02438cba1c5-Bartell]; Temple, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=075cf6e3522d41118c57c29df52ba21b-Amy.Wright]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.  
**Attachments:** RE: Request from WI Legislative Staff

Good morning everyone,

The questions from the legislative staffer are in the attached email.

---

**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 4:24 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Thanks!

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**From:** White, Erica  
**Sent:** Tuesday, April 28, 2020 4:22 PM  
**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Susan,

Thank you for getting back to me. I will follow your suggestions and get a direct contact to see what questions they may have.

Thanks,  
Erica

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 4:18 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Subject:** FW: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,  
I hope all is well with you.



We discussed this request internally. As you know, our staff in our office of vaccines is working non-stop on applications for vaccines to fight COVID-19.

Would you please ask Ms. Nicolson for contact information for the Wisconsin State legislative staffer for so you can request specific questions that are of interest for their publication? We will use those questions to decide if it will be more efficient to have a brief (15 min call) at a pre-arranged time or to respond in writing. We don't have any background but if you feel it is appropriate, you can provide the following link on the vaccine approval process as an initial resource <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>

Thanks,  
Susan

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, April 27, 2020 4:50 PM  
**To:** CBER Exec. Sec. <cber\_execsec@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Good afternoon,

IGA received a request from the National Conference of State Legislatures (NCSL) on behalf of a state legislative staffer to speak with someone at FDA about the biologic vaccine licensure process. The person is working on a publication on vaccine development and immunization for the Wisconsin Legislature. Any assistance you can provide with getting a point of contact for the Wisconsin State legislative staffer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



Erica

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**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>  
**Sent:** Monday, April 27, 2020 8:43 AM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** Request from Legislative Staff

Good Morning Chris,

We got a request from legislative staff to speak with someone at FDA about the biologic vaccine licensure process. He is working on a publication on vaccine development and immunization for the Wisconsin Legislature. He asked if we could speak to someone this week which I told my colleagues who got this request that might be a stretch with all that is going on. Let me know what you advise and I appreciate any resources you all can share.

Thank You!

Haley Nicholson  
National Conference of State Legislatures  
Senior Policy Director, Health & Human Services  
State-Federal Affairs  
202-624-8662 (o)



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**From:** Peddicord, Sarah [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=225D83CC787341DEB87D23AC33B6FB6C-SARAH.PEDDI]  
**Sent:** 4/29/2020 4:18:40 PM  
**To:** Peddicord, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=225d83cc787341deb87d23ac33b6fb6c-Sarah.Peddi]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Busch, Marcy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec4ef9f06a684cafbe4307486233609e-Marcy.Busch]; Mednick, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba9faf32217141efaf6904d00b795eb2-David.Medni]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; Gibney, Jaycie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=390bd4f246ee4a97ada93d146d6d7276-Jaycie.Gibn]; Beaver, Renee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a77c584a71354ff78f66ccd04147c299-Renee.Beave]; Lowe, Toby A [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58547e0b75924310b6ca179ffd40bffa-TAL]; O'Leary, Brendan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8d013e357f314a47bb52078aa21c070a-BJO]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]; MacLennan, Lori [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7e3684d6a36e4002bc07015b7506b803-Lori.MacLen]; Pagan Motta, Monica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39552e3b45c741f19b0bebbf796d96c2-Monica.Paga]; Seligson, Edie D. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39c00b63d10740d4a0f8a8296522a657-EDP]; Ford, Kemba D. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=368c065b2def4d0791ab71a57283b62f-KDF]; Schulken, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6220ca7204a440c18eff33d2e85098db-Susan.Schul]; Flamberg, Gemma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bbcd7049351f49009ec2ebc1efbd5513-Gemma.Flamb]; Singleton, Shannon [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b70632897eee4a66a8e6bf7681210a85-Shannon.Chi]; Taylor, Paige [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f46091afaf2483abb72d8db96066f15-PTaylor]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Johnson, Matia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=847649388ddd4457a023af0450224136-Matia.Johns]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056accc4bc98fdb07bb0548dc86-Paul.Aguila]; Schuck, Brittany [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f10760fd057841df8366bdbbc69de7aff-Brittany.Sc]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Wallace, Tammy D [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c4604538b39a42f3a342de74537868d3-TDW]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Paulos, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5dfb1daac9c14aab8649e6c66087f956-AubrieLaure]; McBride, Maren

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ORA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0b43234cda54a8d8d176cce6651f302-2019-nCoV F]

**CC:** Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Roth, Lauren  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Carrera, Krysten  
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3c23578f55314eae9e03cbc995565b1c-Krysten.Car]

**Subject:** Rollout Touchbase: Serology Policy Check-In

**Attachments:** 20200428 Hahn Statement March Policy Update\_CDRHClear.docx; 2020.04.30\_Fast Facts \_Serological Test Oversight and Use-CDRHClear.docx; 2020.04.30.KMQASerologyMarchPolicyUpdateDRAFT\_CDRHClear.docx; Comms Plan\_Serology Test Policy Update\_April2020OCAOL.docx

**Location:** WebEx

**Start:** 5/1/2020 11:00:00 AM

**End:** 5/1/2020 11:30:00 AM

**Show Time As:** Busy

**Required Attendees:** Hillebrenner, Elizabeth J; Busch, Marcy; Mednick, David; Dennis, Claire; Gibney, Jaycie; Beaver, Renee; Lowe, Toby A; O'Leary, Brendan; Guram, Jeet; MacLennan, Lori; Pagan Motta, Monica; Seligson, Edie D.; Ford, Kemba D.; Schulken, Susan; Flamberg, Gemma; Singleton, Shannon; Taylor, Paige; Flannery, Ellen; Johnson, Matia; Aguilar, Paul; Schuck,

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Brittany; Caccamo, Stephanie; White, Erica; Wallace, Tammy D; Meister, Karen G; Paulos, Lauren; McBride, Maren; Gross, Karas; Anderson, Erika; Alexander, Nicholas; Roberts, Michelle; Shuren, Jeff; 2019-nCoV FDA IMG JIC CDRH; Stenzel, Timothy; Tomasello, Jennifer; Lynch, Sarah; Rebello, Heidi; Caliguiri, Laura; Stark, Angela; Spaulding, Emma; Cristinzio, Dayle; Walsh, Sandy; Tantillo, Andrew; 2019-nCoV FDA IMG JIC ORA

**Optional Attendees:** Block, Molly; Roth, Lauren (Lauren.Roth@fda.hhs.gov); Carrera, Krysten

+ CDRH-cleared/edited materials. KMQA has notes that need to be resolved with CDRH. We will be starting JIC/OCC clearance following this call – these materials **are for awareness only. (Comms Plan, Statement, KMQA, Fact Sheet)**

Note: Invite list includes CDRH SMEs, leadership + Comms (JIC listserv is CDRH JIC members only); OMA/OEA; IGA; OL; OCA; OCC; OPLIA and CoS (Jeet). Please forward to anyone else who should be tracking.

**Agenda:**

- Timing Update (not likely for Thurs)
- Comms status (Statement, KMQA, Fact Sheet)
- Outreach plans:
  - Federal agency partners
  - States/local
  - Stakeholders
  - Press
  - Other

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**CC:** Block, Molly [Molly.Block@fda.hhs.gov]; Roth, Lauren [Lauren.Roth@fda.hhs.gov]  
**Subject:** Rollout Touchbase: Serology Policy Check-In  
**Attachments:** 20200428 Hahn Statement March Policy Update\_CDRHClear.docx; 2020.04.30\_Fast Facts \_Serological Test Oversight and Use-CDRHClear.docx; 2020.04.30.KMQASerologyMarchPolicyUpdateDRAFT\_CDRHClear.docx; Comms Plan\_Serology Test Policy Update\_April2020.docx  
**Location:** WebEx  
**Start:** 5/1/2020 11:00:00 AM  
**End:** 5/1/2020 11:30:00 AM  
**Show Time As:** Busy  
**Required Attendees:** Hillebrenner, Elizabeth J; Busch, Marcy; Mednick, David; Dennis, Claire; Gibney, Jaycie; Beaver, Renee; Lowe, Toby A; O'Leary, Brendan; Guram, Jeet; MacLennan, Lori; Pagan Motta, Monica; Seligson, Edie D.; Ford, Kemba D.; Schulken, Susan; Flamberg, Gemma; Singleton, Shannon; Taylor, Paige; Flannery, Ellen; Johnson, Matia; Aguilar, Paul; Schuck, Brittany; Caccomo, Stephanie; White, Erica; Wallace, Tammy D; Meister, Karen G; Paulos, Lauren; McBride, Maren; Gross, Karas; Anderson, Erika; Alexander, Nicholas; Roberts, Michelle; Shuren, Jeff; 2019-nCoV FDA IMG JIC CDRH; Stenzel, Timothy; Tomasello, Jennifer; Lynch, Sarah; Rebello, Heidi; Caliguiri, Laura; Stark, Angela; Spaulding, Emma; Cristinzio, Dayle; Walsh, Sandy; Tantillo, Andrew  
**Optional Attendees:** Block, Molly; Roth, Lauren (Lauren.Roth@fda.hhs.gov)

+ CDRH-cleared/edited materials. KMQA has notes that need to be resolved with CDRH. We will be starting JIC/OCC clearance following this call – these materials **are for awareness only. (Comms Plan, Statement, KMQA, Fact Sheet)**

Note: Invite list includes CDRH SMEs, leadership + Comms (JIC listserv is CDRH JIC members only); OMA/OEA; IGA; OL; OCA; OCC; OPLIA and CoS (Jeet). Please forward to anyone else who should be tracking.

**Agenda:**

- Timing Update (not likely for Thurs)
- Comms status (Statement, KMQA, Fact Sheet)
- Outreach plans:
  - Federal agency partners
  - States/local
  - Stakeholders
  - Press
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**To:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gome]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: OL Reactive TP's for COVID Briefings  
**Attachments:** Reactive TPs 4.29.20.docx

fyi

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**From:** Tantillo, Anfyidrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Wednesday, April 29, 2020 5:24 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Cc:** Adleberg, Jill <Jill.Adleberg@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Burns, Corey <Corey.Burns@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Feingold, Daniel <Daniel.Feingold@fda.hhs.gov>; George, Bryan <Bryan.George@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Lexer, Susan <Susan.LexerSmith@fda.hhs.gov>; Lockheed, Matthew <Matthew.Lockheed@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Rosebraugh, Sydney <Sydney.Rosebraugh@fda.hhs.gov>  
**Subject:** OL Reactive TP's for COVID Briefings

Attached are OL's Reactive Talking Points, updated through 5pm today.

Thank you.

**Andrew Tantillo, J.D.**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
301-796-8919 M (b)(6)  
andrew.tantillo@fda.hhs.gov



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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
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**Subject:** White House IGA Mtg with State AGs - see Agenda attached for info

**Attachments:** E6FE413B-954F-432D-85E7-3571EFB80603.pdf

**Location:** 1-877-369-5243 P (b)(6)

**Start:** 4/30/2020 2:00:00 PM

**End:** 4/30/2020 3:00:00 PM

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**Optional Attendees:** Brown, Akeisha; Campbell, Christopher; Gomez, Rachel A.; White, Erica

If you are interested.....

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
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**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**CC:** Brown, Akeisha [Akeisha.Brown@fda.hhs.gov]; Campbell, Christopher [Christopher.Campbell@fda.hhs.gov]; Gomez, Rachel A. [Rachel.Gomez@fda.hhs.gov]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Alexander, Nicholas [Nicholas.Alexander@fda.hhs.gov]; Schipper, Jodi [jodi.schipper@fda.hhs.gov]  
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**Attachments:** E6FE413B-954F-432D-85E7-3571EFB80603.pdf  
**Location:** 1-877-369-5243 P( (b)(6) )  
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**Required Attendees:** Meister, Karen G  
**Optional Attendees:** Brown, Akeisha; Campbell, Christopher; Gomez, Rachel A.; White, Erica; Alexander, Nicholas; Schipper, Jodi

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**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
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**Optional Attendees:** Brown, Akeisha; Campbell, Christopher; Gomez, Rachel A.; White, Erica

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**CC:** Brown, Akeisha [Akeisha.Brown@fda.hhs.gov]; Campbell, Christopher [Christopher.Campbell@fda.hhs.gov]; Gomez, Rachel A. [Rachel.Gomez@fda.hhs.gov]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Alexander, Nicholas [Nicholas.Alexander@fda.hhs.gov]

**Subject:** White House IGA Mtg with State AGs - see Agenda attached for info

**Attachments:** E6FE413B-954F-432D-85E7-3571EFB80603.pdf

**Location:** 1-877-369-5243 PG (b)(6)

**Start:** 4/30/2020 2:00:00 PM

**End:** 4/30/2020 3:00:00 PM

**Show Time As:** Tentative

**Required Attendees:** Meister, Karen G

**Optional Attendees:**

Brown, Akeisha; Campbell, Christopher; Gomez, Rachel A.; White, Erica; Alexander, Nicholas

**Attendees:**

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
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**CC:** Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.A]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gome]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: Final NAAG Call Agenda Attached  
**Attachments:** COVID-19 Briefing Call with America's State Attorneys General 04.30.2020 v1.5.pdf

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**From:** Barbknecht, Nick EOP/WHO (b)(6)  
**Sent:** Wednesday, April 29, 2020 6:52 PM  
**To:** Crozer, William F. EOP/WHC (b)(6); Douglas, Danielle E. (OLA) <Danielle.E.Douglas@usdoj.gov>; asmith@ftc.gov; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Final NAAG Call Agenda Attached

Nick Barbknecht  
Associate Director  
White House Office of Intergovernmental Affairs  
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**Sent:** 4/30/2020 8:02:12 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; kalanikaneko@gmail.com; emais.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 29, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA issued a Consumer Update, Tips on Good Nutrition and Using the Updated Nutrition Facts Label During the Coronavirus Pandemic. The update provides helpful tips on how to use the Nutrition Facts label to learn more about



the foods you have on hand or are purchasing online or in stores, especially if you are purchasing different foods because of temporary disruptions in the food supply chain or are buying more canned or packaged foods instead of fresh.

- With support from the FDA's Office of Criminal Investigations and Office of the Chief Counsel, the U.S. Department of Justice announced today that a federal court in Utah has entered an injunction halting the sale of various silver products, promoted as treatments for COVID-19.

- "The FDA will continue to help ensure those who place profits above the public health during the COVID-19 pandemic are stopped," said **Judy McMeekin, Pharm.D., FDA Associate Commissioner for Regulatory Affairs**. "We are fully committed to working with the Department of Justice to take appropriate action against those jeopardizing the health of Americans by offering and distributing products with unproven claims to prevent or treat COVID-19."

- The FDA granted accelerated approval to a new dosing regimen for a cancer therapy, to allow patients with certain cancers to continue treatment with fewer in-person visits. Specifically, the new dosing regimen allows patients to visit cancer centers less often while getting the treatment they need. This application was approved more than five months prior to the FDA goal date.

- The FDA issued an Emergency Use Authorization (EUA) for SARS-CoV-2 Antibody Tests that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by FDA, and are confirmed by FDA to meet the criteria set forth in the Scope of Authorization. Under this serology "umbrella" EUA, authorized devices are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies (IgG, or IgG and IgM, or total), as specified in each authorized device's instructions for use, to SARS-CoV-2 in human plasma and/or serum. Emergency use of the authorized devices is limited to the authorized laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 to perform moderate or high complexity tests. Authorized devices will be added to Appendix A and will be posted on the FDA's website.

- The FDA recently posted FAQs on Ventilators, including questions and answers related to the Enforcement Policy on Ventilators and Ventilators added to the "Umbrella" EUA, which added to the existing FAQs on Public Availability (Open Sourcing) of Ventilator Software and Design.

- The FDA also recently posted FAQs on EUAs for Medical Devices During the COVID-19 Pandemic, including how to submit a request for a new EUA and what happens to authorized devices after the public health emergency is over.

- Diagnostics update to date:

- During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.

- To date, the FDA has issued 50 individual emergency use authorizations for test kit manufacturers and laboratories. In addition, 23 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).

- The FDA has been notified that more than 235 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.

- The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

### **Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 4/30/2020 2:43:03 PM  
**To:** Robyn Atkinson-Dunn [rmatkinson@utah.gov]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Re: COVID-19 Serology Testing- Call with FDA

Good afternoon Dr. Atkinson-Dunn,

Dr. Slev indicated that she is available tomorrow after 9:30am CMT to meet with Dr. Guram. Checking to see if you are also available tomorrow for a meeting.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Slev, Patricia <patricia.slev@aruplab.com>  
**Sent:** Thursday, April 30, 2020 1:36 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Robyn Atkinson-Dunn <rmatkinson@utah.gov>; Nathan Checketts <nchecketts@utah.gov>  
**CC:** Gordon Larsen <gordonlarsen@utah.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Re: COVID-19 Serology Testing- Call with FDA

Good Morning,  
I am available tomorrow , 5/1 after 9:30 am CMT.  
Thank you,

Patricia Slev, D(ABCC)  
Section Chief Immunology Division  
Medical Director Core immunology  
Medical Director Microbial Immunology  
Medical Director Serologic Hepatitis and Retrovirus Laboratory

Associate Professor of Pathology, University of Utah  
patricia.slev@aruplab.com  
801-583-2787 ext 3253

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, April 30, 2020 9:07 AM  
**To:** Slev, Patricia <patricia.slev@aruplab.com>; Robyn Atkinson-Dunn <rmatkinson@utah.gov>; Nathan Checketts

<nchecketts@utah.gov>

Cc: Gordon Larsen <gordonlarsen@utah.gov>; White, Erica <Erica.White@fda.hhs.gov>

Subject: RE: Re: COVID-19 Serology Testing- Call with FDA

**Attention: This email came from an external source. Do not open attachments or click on links from unknown senders or unexpected emails.**

Thanks Nate for connecting us all.

Drs. Slev and Atkinson-Dunn, Dr. Guram is available today and tomorrow anytime EXCEPT:

4/30

11:45am-12:15pm

3pm-4pm

5/1

9am-9:30am

11am-11:45am

3:30pm-4pm

Please let us know what times work for you and we are happy to set up the call and send a call-in number for you.

Thank you all for your time and consideration.

Karen

*Karen Meister, J.D.*

*Acting Director, Intergovernmental Affairs*

*Senior Advisor, Office of Legislation*

*Office of the Commissioner/OPPLIA*

*U.S. Food and Drug Administration*

*(301) 796-8916 office*

*(240) 494-6228 (work cell)*

*[REDACTED] (b)(6) [REDACTED] (personal cell- I will call you back on work phone)*

**From:** Nathan Checketts <nchecketts@utah.gov>

**Sent:** Thursday, April 30, 2020 9:31 AM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Cc:** Slev, Patricia <patricia.slev@aruplab.com>; Robyn Atkinson-Dunn <rmatkinson@utah.gov>; Gordon Larsen <gordonlarsen@utah.gov>; White, Erica <Erica.White@fda.hhs.gov>

**Subject:** QAZ: Re: COVID-19 Serology Testing

I apologize that my first message was sent encrypted. Please see the message below:

*Please connect with Patricia Slev, ARUP, and Robyn Atkinson-Dunn, Utah's state lab director, for this discussion. I will try to join if possible but don't wait for me to have the discussion.*

Robyn and Patricia, please let Karen know what times would work for you.

Thanks,

Nate

On Mon, Apr 27, 2020 at 3:08 PM Meister, Karen G <Karen.Meister@fda.hhs.gov> wrote:

Hi All-

Wondering if you all would have time for a call with Dr. Jeet Guram, Senior Advisor in the Food and Drug Administration's FDA's Office of the Commissioner, about serology testing in connection with COVID-19. Please provide times that work for you. Would appreciate if you could respond to this email. Sorry I could not read the email below.

Thank you and I hope you and your families are doing ok during these challenging times.

Karen

*Karen Meister, J.D.*

*Acting Director, Intergovernmental Affairs*

*Senior Advisor, Office of Legislation*

*Office of the Commissioner/OPPLIA*

*U.S. Food and Drug Administration*

*(301) 796-8916 office*

*(240) 494-6228 (work cell)*

**(b)(6)** *personal cell- I will call you back on work phone)*

**From:** Nathan Checketts <nchecketts@utah.gov>

**Sent:** Monday, April 27, 2020 2:56 PM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Cc:** Gordon Larsen <gordonlarsen@utah.gov>; White, Erica <Erica.White@fda.hhs.gov>; Slev, Patricia <patricia.slev@aruplab.com>; Robyn Atkinson-Dunn <rmatkinson@utah.gov>

**Subject:** Re: COVID-19 Serology Testing

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**Sent:** 4/30/2020 4:35:19 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Hey,

Since the ones that FDA can answer are mostly for CDER, so you want to take the lead?

---

**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>  
**Sent:** Thursday, April 30, 2020 4:18 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Follow Up Questions from Vaccine Webinar

Good Afternoon Chris and Erica,

I first want to say a huge thanks for all you and your team has helped us with during this time. Below are the questions that came in for Dr. Shah during the webinar but we obviously didn't have time to get to all of them. Would you all be able to take a look and provide any answers that you can? Understandably you may not be able to answer all of them or if some are more directing our members to a resource to read up on we would welcome that. Let me know if you have any questions and thank you again for all you have done for our members and staff!

- It was reported that Oxford University is testing a vaccine that could be available by August of 2020, This would be an incredibly rapid turnaround for a vaccine. Do you feel this might in fact happen? FDA shouldn't comment
- Even if an effective and safe vaccine is developed, how long would it take to produce and distribute it to large parts of the U.S. population?
- What is the actual number of weeks or months on the fast track program?
- What is the timeline for therapies?
- What kind of outreach is used in the Latino Hispanic communities? Clinical trial outreach is not within FDA's purview.
- Have there been challenges with participation of Hispanics and African Americans in the clinical trials, as often is the case with the development of other vaccines/medications? Clinical trial participation is not within FDA's purview.
- Have there been any supply challenges on the use of existing medicines to treat and/or alleviate symptoms of Covid 19? Can you provide us an brief example of such?
- After talking to some physicians on the ER front lines I have the following question: Is there any protocol (or upcoming protocol) for prophylactic use of medications for healthcare professionals dealing with COVID-19 patients? There is apparently a great deal of confusion among them about this.

Thank You,

Haley Nicholson  
National Conference of State Legislatures  
Senior Policy Director, Health & Human Services  
State-Federal Affairs  
202-624-8662 (o)



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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 5/1/2020 8:15:13 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@salud.pr.gov; emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for April 30, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA included, under the ventilator emergency use authorization (EUA), a ventilator developed by the National Aeronautics and Space Administration (NASA), which is tailored to treat patients with COVID-19. The ventilator

was added to the list of authorized ventilators, ventilator tubing connectors and ventilator accessories under the ventilator EUA that was issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in health care settings to treat patients during the COVID-19 pandemic. The NASA VITAL (Ventilator Intervention Technology Accessible Locally) is intended to last three to four months and is specifically tailored for patients with COVID-19, by providing respiratory support for patients that are experiencing respiratory failure or insufficiency. The device is designed to be built with components outside the current medical device supply chain and therefore does not impact the existing supply chain of currently made ventilators.

- The FDA issued a Consumer Update, [Helpful Questions and Answers about Coronavirus \(COVID-19\) and Your Pets](#), that provides answers to frequently asked questions. Based on the limited information available to date, the risk of pets spreading the virus that causes COVID-19 in people is considered to be low. At this time, there is no evidence that animals play a significant role in spreading the virus that causes COVID-19. There is a small number of animals around the world reported to be infected with the virus that causes COVID-19, mostly after having close contact with a person with COVID-19.
- The FDA issued a guidance highlighting flexibility under the Drug Supply Chain Security Act (DSCSA). This guidance is intended to facilitate the distribution of prescription drug products needed to respond to COVID-19, including drugs to treat symptoms of COVID-19. During the COVID-19 emergency, the DSCSA requirements related to certain product tracing and product identification activities, and wholesale distribution, do not apply to qualifying distribution activities. This flexibility balances the need for effective distribution of products under emergency conditions with protecting consumers from exposure to products that may be counterfeit, stolen or otherwise harmful.
- **Diagnostics Update to Date**
  - During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting emergency use authorizations (EUA) requests to FDA for tests that detect the virus.
  - To date, the FDA has issued 53 individual emergency use authorizations for test kit manufacturers and laboratories. In addition, 23 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 235 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

#### **Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)



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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 5/4/2020 10:17:55 AM  
**To:** Garner, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ffc21ad80bf94e879d0e8fa3dafb0dbc-Kimberly.Ga]  
**Subject:** RE: [External] **(b)(4)** SC Manufacturing Company Information

Thank you Kimberly.

Erica

---

**From:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 10:16 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: [External] **(b)(4)** SC Manufacturing Company Information

Good Morning, Erica,

Perhaps you've already provided a response to the original inquirer regarding this RFI, but Planning received the following response from CDRH this morning in case it's still helpful:

**(b)(4) (b)(5)**

(b)(4) (b)(5)

Kind Regards,

Best,  
Kim

Kim Garner  
LCDR, U.S. Public Health Service  
Interagency Information Liaison/RFI Triage  
2019 Novel Coronavirus (COVID-19) IMG  
U.S. Food and Drug Administration  
**Desk:** 240-402-6549  
**Cell:** (b)(6)  
**Email:** kimberly.garner@fda.hhs.gov  
**IMG Planning Section email:**  
2019-nCoVFDAIMGPlanning@fda.hhs.gov

---

**From:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 3:52 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV  
FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Hello Erica,

IMG Planning will route this inquiry to the appropriate office for follow-up.

Thank you.

Vanessa Williams  
RFI Triage  
Planning Section  
FDA COVID-19 IMG  
Office: 301-796-8262  
Cell (b)(6)  
24-Hour Telephone: 301-796-8240 or 866-300-4374  
email: vanessa.williams@fda.hhs.gov

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---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 3:48 PM

**To:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Hi Vanessa,

Below is a question from SC regarding (b)(4) Any assistance with getting an answer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** White, Erica

**Sent:** Wednesday, April 1, 2020 11:46 AM

**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Hi Jennifer,

The question below is about hospital beds. I have the CDRH website regarding hospital beds, but I haven't seen anything related to beds and COVID. Any assistance you can provide with an answer would be greatly appreciated.

Erica

---

**From:** Marsh, Jordan <JMarsh@governor.sc.gov>

**Sent:** Tuesday, March 31, 2020 9:11 AM

**To:** IGA <IGA@fda.hhs.gov>

**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

We have (b)(4) company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make

(b)(4) ?

Best,

Jordan Marsh

Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
[jmarsh@governor.sc.gov](mailto:jmarsh@governor.sc.gov)

---

**From:** Sarah Hearn <[SarahHearn@schouse.gov](mailto:SarahHearn@schouse.gov)>  
**Sent:** Wednesday, March 25, 2020 10:13 AM  
**To:** Marsh, Jordan <[JMarsh@governor.sc.gov](mailto:JMarsh@governor.sc.gov)>  
**Subject:** [External: (b)(4)] Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, Ms. (b)(4) has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4) Contact is  
(b)(4) cell; (b)(6) Best to call (b)(4) cell. We currently manufacture (b)(4)  
(b)(4) We sell to (b)(4) Due to many of the retail stores closing, we  
have decided to convert the factory over to making PPE.

First, we are currently set up to make (b)(4)  
(b)(4)

(b)(4) Second, we are planning to make face masks. I have already started ordering the supplies for these

(b)(4)

(b)(4) I have not started any research on those items yet. Any help on how to make them and approved  
(b)(4) would be very useful. I have spoken to a vendor that I buy supplies from for our (b)(4) and she said  
they have (b)(4) Need to make sure FDA approves before I order it.

(b)(4)

Thank You,

**(b)(4)**

Sarah Hearn

Research/Budget Analyst

Ways and Means Committee

S.C. House of Representatives

(803) 734-1577

---

**From:** Brown, Akeisha [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=802C3F43976C4EAE88F559C26CB51BE5-AKEISHA.BRO]  
**Sent:** 5/4/2020 11:02:33 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Closed out in the tracker.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 10:19 AM  
**To:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Good morning Akeisha,

This inquiry is now complete.

Erica

---

**From:** Garner, Kimberly <Kimberly.Garner@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 10:16 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Good Morning, Erica,

Perhaps you've already provided a response to the original inquirer regarding this RFI, but Planning received the following response from CDRH this morning in case it's still helpful:

(b)(4) (b)(5)

(b)(4) (b)(5)

Kind Regards,

Best,  
Kim

Kim Garner  
LCDR, U.S. Public Health Service  
Interagency Information Liaison/RFI Triage  
2019 Novel Coronavirus (COVID-19) IMG  
U.S. Food and Drug Administration  
**Desk:** 240-402-6549  
**Cell:** (b)(6)  
**Email:** kimberly.garner@fda.hhs.gov  
**IMG Planning Section email:**  
2019-nCoVFDAIMGPlanning@fda.hhs.gov

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**From:** Williams, Vanessa <Vanessa.Williams@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 3:52 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV  
FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>  
**Subject:** RE: [External] (b)(4) SC Manufacturing Company Information

Hello Erica,

IMG Planning will route this inquiry to the appropriate office for follow-up.

Thank you.

Vanessa Williams  
RFI Triage

Planning Section  
FDA COVID-19 IMG  
Office: 301-796-8262  
Cell: (b)(4)  
24-Hour Telephone: 301-796-8240 or 866-300-4374  
email: [vanessa.williams@fda.hhs.gov](mailto:vanessa.williams@fda.hhs.gov)

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---

**From:** White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>  
**Sent:** Wednesday, April 1, 2020 3:48 PM  
**To:** Williams, Vanessa <[Vanessa.Williams@fda.hhs.gov](mailto:Vanessa.Williams@fda.hhs.gov)>  
**Cc:** Tomasello, Jennifer <[Jennifer.Tomasello@fda.hhs.gov](mailto:Jennifer.Tomasello@fda.hhs.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Hi Vanessa,

Below is a question from SC regarding (b)(4). Any assistance with getting an answer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** White, Erica  
**Sent:** Wednesday, April 1, 2020 11:46 AM  
**To:** Tomasello, Jennifer <[Jennifer.Tomasello@fda.hhs.gov](mailto:Jennifer.Tomasello@fda.hhs.gov)>  
**Cc:** Pennington, Caitlin <[Caitlin.Pennington@fda.hhs.gov](mailto:Caitlin.Pennington@fda.hhs.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>; Paulos, Lauren <[Lauren.Paulos@fda.hhs.gov](mailto:Lauren.Paulos@fda.hhs.gov)>  
**Subject:** FW: [External] (b)(4) SC Manufacturing Company Information

Hi Jennifer,

The question below is about (b)(4). I have the CDRH website regarding (b)(4) but I haven't seen anything related to (b)(4) and COVID. Any assistance you can provide with an answer would be greatly appreciated.

Erica



---

**From:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Sent:** Tuesday, March 31, 2020 9:11 AM  
**To:** IGA <IGA@fda.hhs.gov>  
**Subject:** FW: [External] (b)(4), SC Manufacturing Company Information

We have a (b)(4) company in South Carolina that is working to convert their facility to medical supply manufacturing. Can you please provide information or a contact who can assist the company with providing the FDA guidelines to make (b)(4) }

Best,

Jordan Marsh  
Director of Federal Affairs  
Office of Governor Henry McMaster  
State of South Carolina  
(803) 509-0581  
jmarsh@governor.sc.gov

---

**From:** Sarah Hearn <SarahHearn@schouse.gov>  
**Sent:** Wednesday, March 25, 2020 10:13 AM  
**To:** Marsh, Jordan <JMarsh@governor.sc.gov>  
**Subject:** [External] (b)(4) Manufacturing Company Information

Jordan,

Thanks for your patience yesterday on what was probably one of the vaguest calls you have received over the course of the past week. Hopefully, the quoted information below provides context on the company's needs/goals for seeking FDA approval.

For what it's worth, Ms (b)(4) has been in touch with Gene Smith at the SC Manufacturing Extension Partnership about getting on their list of companies who want to convert to medical supply manufacturing. SCMEP is trying to keep too many companies from converting at once by focusing first on the companies who already have the ability to make medical supplies. After that, they will help other companies convert to medical manufacturing. Let me know if you need any further details from the constituent.

Thanks,  
Sarah

(b)(4) Contact is  
(b)(4) cell (b)(6) Best to call (b)(6) cell. We currently manufacture (b)(4)  
(b)(4) We sell to (b)(4) Due to many of the retail stores closing, we  
have decided to convert the factory over to making PPE.  
First, we are currently set up to make (b)(4)  
(b)(4)

**(b)(4)** Second, we are planning to make face masks. I have already started ordering the supplies for these masks; **(b)(4)**

**(b)(4)**

In conclusion, I am working diligently to get this project up and running. I just need the approval from FDA on the **(b)(4)** and a connection to sell these products. Any assistance, guidance, or advice will be greatly appreciated.

Thank You,

**(b)(4)**

Sarah Hearn

Research/Budget Analyst

Ways and Means Committee

S.C. House of Representatives

(803) 734-1577

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 5/5/2020 7:21:45 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); jemailis.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for May 4, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration yesterday announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- A new FDA Voices, [Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy](#), explains today's update to a policy from March 16, 2020 on antibody tests for COVID-19. The FDA will continue to take steps to

appropriately balance assurances that an antibody test is accurate and reliable with timely access to such tests as the continually evolving circumstances and public health needs warrant.

- FDA issued warning letters to operators of two websites, [www.antroids.com](http://www.antroids.com) and [www.foxroids.com](http://www.foxroids.com), that market unapproved COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved drugs to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider. Consumers can visit [BeSafeRx](https://www.fda.gov/BeSafeRx) to learn about how to safely buy medicine online.
  
- The FDA authorized the first serology, or antibody, test where the results of a new independent validation effort by the U.S. Government provided the scientific evidence used to support the authorization. The testing was performed at the Frederick National Laboratory for Cancer Research (FNLRCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Institutes of Health's (NIH) National Cancer Institute (NCI). The results are among the first to come from a collaborative effort by the FDA, NIH, Centers for Disease Control and Prevention (CDC), and Biomedical Advanced Research and Development Authority (BARDA) to evaluate certain serological tests. Essential samples and materials used in the evaluation were provided by the NIH National Institute of Allergy and Infectious Diseases (NIAID), the Mount Sinai Health System, the Icahn School of Medicine at Mount Sinai, including members of the Departments of Microbiology and Pathology, and the Vitalant Research Institute.
  
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 380 test developers who have said they will be submitting EUA requests to the FDA for tests that detect the virus.
  - To date, the FDA has issued 58 individual EUAs for test kit manufacturers and laboratories. In addition, 25 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 235 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

---

**Sent:** 5/5/2020 7:26:26 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; Gras, Ruth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=896294988ddc451f93b1073f119943af-Ruth.Gras]  
**Subject:** RE: Town Hall Wed?

FYI, Ruth already sent out an invite for the Wednesday Town Hall to the state health depts.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 8:10 PM  
**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

(b)(5)

Meanwhile I'll ask Jennifer to give us a couple of times Jeff could be available. Of course, if someone can't make it, they can listen to the Wed town hall and just not be able to ask questions.

Thoughts?

Karen

---

**From:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Sent:** Monday, May 04, 2020 7:20 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

What do you all think?

One one hand, the call is already scheduled and it would be easy to link on.

(b)(5)

Whatever the case, make sure to invite ASTHO and APHL.

Hope this is all helpful.

— Nick

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** May 4, 2020 at 6:25:58 PM EDT  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Ruth. Did you already send an email with time for town hall ?

If so I think we should proceed. (b)(5)

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Date:** May 4, 2020 at 5:00:40 PM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Karen,

We do not have a preference (b)(5)  
(b)(5)  
(b)(5) Just let us know what you think is best  
in terms of outreach to them.

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



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

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 4:53 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

(b)(5)

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**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Date:** May 4, 2020 at 4:06:38 PM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Hi Karen,

We are fine scheduling a call with the state health departments. Let me know what you need from us. Do you need some times that Jeff would be available?

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**  
*Senior Policy Advisor*

Center for Devices and Radiological Health  
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U.S. Food and Drug Administration  
Tel: 301-796-8924 - Cell: (b)(6)  
jennifer.tomasello@fda.hhs.gov



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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Monday, May 4, 2020 10:45 AM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** FW: Town Hall Wed?

Hi Jennifer-

That is what we think is best. Do we need to get you any other OC confirmation or is this request enough for you to proceed?

Thanks Jennifer.

Karen

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**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Monday, May 04, 2020 7:42 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Karen and Nick,

I'm happy to see if we can do this; these calls are up to OC so if this is what you all think is best in terms of our outreach, let me know.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**  
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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Sunday, May 3, 2020 11:56 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Fwd: Town Hall Wed?

Nick suggest: (b)(5) our thoughts?

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**From:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>



**Date:** May 3, 2020 at 11:44:12 PM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

(b)(5)

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**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Date:** May 3, 2020 at 10:22:55 PM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Hi! Yes these calls are up to OC so fine with us if you want to take that approach. I'll give Tim a heads up that there are likely to be a lot of state health depts on Weds.

Thanks again for sending me the invite for the gov call tomorrow.

Best,

Jennifer

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** May 3, 2020 at 9:02:13 PM EDT  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Thanks Jennifer.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Sunday, May 03, 2020 9:01 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Yes I understand; will keep you posted!

And Hi Ruth! Good to see you, too. Its been a while. 😊

Jennifer

**Jennifer Brown Tomasello, MPA**  
*Senior Policy Advisor*

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Sunday, May 3, 2020 9:00 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Dept of Health

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Sunday, May 03, 2020 8:30 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

I will ask; as long as its not the state constitutional offices or local legislators calling in, I'd expect it to be fine but let me be sure.

CDRH sends a message out each week reminding folks about the town halls, I believe. They are also posted on the website.

More to come,

Jennifer

**Jennifer Brown Tomasello, MPA**  
*Senior Policy Advisor*

Center for Devices and Radiological Health  
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U.S. Food and Drug Administration  
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jennifer.tomasello@fda.hhs.gov



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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Sunday, May 3, 2020 8:12 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Could we invite State Health Depts to listen and ask questions too? I think Public Lab Assn will be on stakeholder call tomorrow.

Does an invitation go out every week or do developers just know to go to website?

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Sunday, May 03, 2020 7:03 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Town Hall Wed?

Karen,

I expect the updated policy will be covered, yes. This is one of our weekly town hall meetings where Tim Stenzel and others address questions from developers about COVID 19 testing. So we would invite the state governments to call in and ask questions? Or just the developers within their states? We don't allow Congressional offices or the press to ask questions on these town halls; anyone can call in to listen (and we know House oversight staff are doing this already) but only developers can ask questions.

Best,

Jennifer

**Jennifer Brown Tomasello, MPA**  
*Senior Policy Advisor*

Center for Devices and Radiological Health  
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*<https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E>*

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Sunday, May 3, 2020 6:59 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Town Hall Wed?

Jennifer-

I presume the CDRH Town Hall Wed will talk about the new serology guidance

(b)(5)

(b)(5)

We can outreach the town hall if it will cover this. Thank you! Karen

---

**Sent:** 5/5/2020 2:09:57 PM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**Subject:** RE: Governor of Oregon - Department R/C

Thanks Jennifer.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Tuesday, May 5, 2020 2:09 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Hi sorry, will try to get this done soon.

**Jennifer Brown Tomasello, MPA**  
*Senior Policy Advisor*

Center for Devices and Radiological Health  
Office of Policy  
U.S. Food and Drug Administration  
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jennifer.tomasello@fda.hhs.gov



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

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Tuesday, May 5, 2020 2:08 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Hi Jennifer,

Checking on the status of this request.

Erica

---

**From:** White, Erica  
**Sent:** Tuesday, April 28, 2020 1:19 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** FW: Governor of Oregon - Department R/C

Hi Jennifer,

Do you have an update on the status of this request.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** White, Erica

**Sent:** Thursday, April 2, 2020 4:20 PM

**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** FW: Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Good afternoon everyone,

FDA has been asked to prepare a response to Governor Kate Brown who writes about Oregon's need for sufficient personal protective equipment (PPE) and ventilators to assist with the COVID-19 epidemic. IGA has drafted an initial response. CDRH and the JIC, please review and clear the attached draft by COB, Monday, April 6.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



**From:** aimssystem@fda.hhs.gov <aimssystem@fda.hhs.gov>

**Sent:** Thursday, April 2, 2020 7:21 AM

**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>

**Subject:** Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Note: Do NOT reply directly to this E-mail

A referral has been sent to your office by FDA/OC/OES/ on Correspondence Control # 2020-1492 requesting your assistance. A summary of the referral appears below. If you have any questions, please contact WANDA G. RUSS of FDA/OC/OES/.

Action:

Due Date:

Synopsis:

**Prepare Response for  
Signature  
Tuesday, April 7, 2020  
Department D/R for  
Commissioner Sig and  
Department R/C Governor  
Brown writes about  
Oregon's need for  
sufficient personal  
protective equipment  
(PPE) and ventilators to  
assist with the COVID-19  
epidemic.**

Please click the URL below to access the referral:

[http://aims.fda.gov/cktoken/ct\\_token.mainPage?p\\_token=sg8h1r70j03k570c3cm00000gzqfu60000158rjbmngyp82330luis283r589ern](http://aims.fda.gov/cktoken/ct_token.mainPage?p_token=sg8h1r70j03k570c3cm00000gzqfu60000158rjbmngyp82330luis283r589ern)

You can view the original correspondence by clicking the button 'View Orig Corr' (if available). After reviewing all the information provided, please acknowledge receipt of the referral by clicking either the ACCEPT button or the DECLINE button.

If you ACCEPT the referral, a new COMPLETE button is immediately displayed. You can either:

Click the COMPLETE button to complete the referral now

OR

You MUST retain this e-mail with the above URL until you have completed the referral request. Click the above URL again and click the COMPLETE button.

---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 5/5/2020 9:07:13 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@salud.pr.gov; emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for May 5, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:



- The FDA and Federal Trade Commission (FTC) issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
  - The first seller warned, Honey Colony LLC, offers products including "Quicksilver Liposomal Vitamin C w/ Liposomal," "Jigsaw Magnesium With SRT," and products labeled to contain silver, including "Silver Excelsior Serum", for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19.
  - The second seller warned, Dr. Dhole's Sushanti Homeopathy Clinic, offers products including "Homeopathic Genus Epidemicus" for sale in the U.S. with misleading claims that the product is safe and/or effective for the prevention of COVID-19.
- Yesterday, FDA approved two generic drugs indicated to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation: succinylcholine chloride injection USP 200 mg/10 mL and cisatracurium besylate injection USP 20 mg/10 mL. FDA recognizes the increased demand for certain products during the novel coronavirus pandemic and we remain deeply committed to facilitating access to medical products to help address critical needs of the American public.
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 385 test developers who have said they will be submitting EUA requests to the FDA for tests that detect the virus.
  - To date, the FDA has issued 59 individual EUAs for test kit manufacturers and laboratories. In addition, 25 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 240 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- Coronavirus Disease 2019 [COVID-19]

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 5/8/2020 12:20:18 AM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup for May 7, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:

- The FDA provided an update on the Agency's efforts to combat the extremely concerning actions by companies and individuals that are exploiting or taking advantage of widespread fear among consumers during the COVID-19

pandemic. In response to scammers on the internet selling unproven medical products, the FDA has taken – and continues to take – a number of steps to find and stop those selling unapproved products that fraudulently claim to mitigate, prevent, treat, diagnose or cure COVID-19.

- The FDA and Federal Trade Commission (FTC) issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
  - The first seller warned, Alive By Nature, Inc., offers "NAD+" and "NMN" sublingual gel products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19.
  - The second seller warned, GlutaGenic, offers Viral Protection Kits for sale U.S. with misleading claims that the products in the kits are safe and/or effective for the prevention of COVID-19.
- The FDA shared the first test report and detailed data from the independent validation study performed at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center sponsored by the National Institutes of Health's (NIH) National Cancer Institute (NCI), which data were used to support an EUA request. The results come from a collaborative effort by the FDA, NIH, Centers for Disease Control and Prevention (CDC), and Biomedical Advanced Research and Development Authority (BARDA) to evaluate certain serological tests. While the EUA request was not granted solely based on the validation data, the data were leveraged to inform FDA's decision making. The NCI FNLCR test report provides new details on the testing that is being performed by NCI. Essential samples and materials used in the evaluation were provided by the NIH National Institute of Allergy and Infectious Diseases, the Mount Sinai Health System, the Icahn School of Medicine at Mount Sinai, including members of the Departments of Microbiology and Pathology, and the Vitalant Research Institute.
- The FDA issued an Emergency Use Authorization (EUA) to Sherlock BioSciences, Inc.'s Sherlock CRISPR SARS-CoV-2 Kit. This test is the first authorized use of CRISPR technology for an infectious disease test. The Sherlock CRISPR SARS-CoV-2 Kit is a CRISPR-based SHERLOCK (Specific High sensitivity Enzymatic Reporter unLOCKing) diagnostic test that looks for the specific target RNA or DNA sequences of the SARS-CoV-2 virus in upper respiratory specimens, such as nasal swabs, and bronchoalveolar lavage specimens, such as from fluid in the lungs, from individuals suspected of COVID-19 by their healthcare provider. Use of the test is limited to laboratories certified under CLIA to perform high-complexity tests.
- The FDA reissued the EUA for non-NIOSH-approved respirators manufactured in China. The FDA updated the eligibility criteria by making a few main changes, including revising one of the criteria that required an accredited and independent lab test to now require that certain respirators previously listed in Appendix A must pass CDC/NIOSH testing, as further explained in the EUA. As part of the government's continuous quality assessment of these respirators, CDC, working with FDA, conducted additional assessments and found that some of the respirators authorized under the April 3, 2020 EUA did not meet the expected performance standards. As a result, the FDA revised and reissued the EUA to remove all firms that were authorized based on the independent lab test criterion. Additionally, the FDA, in collaboration with CDC NIOSH, is increasing surveillance and sampling of all respirators imported from China – all respirator shipments from China that come into the U.S. will be subject to random sampling and testing by CDC NIOSH to determine whether the respirator meets acceptable particulate filtration standard. The FDA is committed to helping health care providers navigate this dynamic situation, and we issued a Letter to Healthcare Providers with considerations for all health care facilities that have respirators in their inventory.
- The FDA issued a Letter to Health Care Providers on Risk of Misinterpreting Hydrogen Peroxide Indicator Colors for Vapour Sterilization. The FDA has become aware of the potential for health care facility staff that reprocess and sterilize medical devices to misinterpret the indicators used to validate the sterilization of medical devices because there is no standard indicator color to indicate a sterilized device. The Agency recommends that health care facility staff review the manufacturer's instructions for their indicators. Each manufacturer has developed its own color scheme to validate the sterilization process, and the colors vary among manufacturers even though many are validated for the same cycle conditions. There have been no injuries reported to the FDA associated with the use of these indicators.
- The FDA issued an immediately in effect guidance, "Reporting and Mitigating Animal Drug Shortages during the COVID-19 Public Health Emergency" to assist animal drug sponsors in submitting timely and informative drug shortage notifications to the FDA. This guidance explains how and why to notify the FDA, and the details to provide about the

discontinuance or interruption of manufacturing and other factors that may impact availability of animal drug products. The guidance also includes examples of steps FDA's Center for Veterinary Medicine may take to prevent or mitigate animal drug shortages, and information sponsors can provide proactively to help avoid shortages.

- The FDA released informational materials for food industry in Spanish, Somali and other languages. This assistance provides food safety best practices for retail food stores, restaurants and food pick-up/delivery services during the COVID-19 pandemic.
  - Spanish resource: What to Do if You Have COVID-19 Confirmed Positive or Exposed Workers in Your Food Production, Storage, or Distribution Operations Regulated by FDA
  - Spanish resource: Use of Respirators, Facemasks, and Cloth Face Coverings in the Food and Agriculture Sector During Coronavirus Disease (COVID-19) Pandemic
  - Somali, Af Soomaali resource: Best Practices for Retail Food Stores, Restaurants, and Food Pick-Up/Delivery Services During the COVID-19 Pandemic
  - Hmong, Hmoob resource: Best Practices for Retail Food Stores, Restaurants, and Food Pick-Up/Delivery Services During the COVID-19 Pandemic
- Diagnostics update to date:
  - During the COVID-19 pandemic, the FDA has worked with more than 385 test developers who have said they will be submitting EUA requests to the FDA for tests that detect the virus.
  - To date, the FDA has issued 63 individual EUAs for test kit manufacturers and laboratories. In addition, 25 authorized tests have been added to the EUA letter of authorization for high complexity molecular-based laboratory developed tests (LDTs).
  - The FDA has been notified that more than 245 laboratories have begun using their own tests under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
  - The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

**Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 5/8/2020 8:40:25 AM  
**To:** Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz\_bohn]; Patel, Bharti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=933ead78c9584fc6bb322f739bdaf5bc-Patelb]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; OC OCOD Contacts [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=502e664f195a4e55ad34e3345edc2005-OC OCOD Con]; Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)  
**Attachments:** OCC Sen Weiner- Convalescent plasma -MSM donors.docx

Good morning everyone,

OCC has reviewed the letter and included some questions for CBER. Once OCC's questions are addressed I will move the letter up the clearance chain.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** White, Erica  
**Sent:** Monday, April 27, 2020 7:45 AM  
**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Susan,

Yes, IGA does send items to OP as well.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



---

**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Friday, April 24, 2020 6:35 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica,

The responses to letters regarding MSM that come through FDA Exec Sec are sent to both OCC and OP for clearance. Bharti mentioned that OCC needed to review the highlighted section because it was not previously cleared. Does IGA routinely send responses through OP?

Thanks,  
Susan

---

**From:** Patel, Bharti  
**Sent:** Friday, April 24, 2020 10:40 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Good morning Erica.

I have attached CBER's response to the inquiry from Senator Weiner. Please note that this response was drafted using language from a response to inquiry from Rep. Quigley that was reviewed by OCC. The response to the inquiry from Senator Weiner was tailored to address the issues identified in his inquiry and has some new language. I have highlighted the section that OCC needs to review.

Thank you for your patience and please let us know if you have any questions.

Best regards,  
Bharti.

*Bharti Patel*  
*Consumer Safety Officer*  
*Congressional and Oversight Branch*  
*Division of Disclosure and Oversight Management*  
*CBER/FDA*

240-402-8138

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:26 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

That works. Thanks for letting me know.

Erica

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:23 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

I am hoping to get it to you in next few days.

Thanks,  
Bharti

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:21 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks for the update. Do you have an estimated time when it might be done, so I can let FDA Exec Sec know?

Erica

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:18 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

The response is still under review within CBER. Can we please get an extension?

Thanks,  
Bharti

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:11 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks Bharti,

That should be fine. Please keep us posted.

Erica

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:10 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

We will try but may need an extension due to other priorities related to COVID-19.

Thanks,  
Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:03 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Bharti,

If possible, can we receive the cleared final version by COB Wednesday?

Erica

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 1:58 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Subject:** FW: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica-

Can you please respond to Bharti? Thanks

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 1:55 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Karen.



Hope all is well. You may be aware of the attached inquiry. We are working on it but we do not know what the due date is. Can you please let us know?

Thanks,  
Bharti

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**Sent:** 5/8/2020 8:56:32 AM  
**To:** Patel, Bharti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=933ead78c9584fc6bb322f739bdaf5bc-Patelb]  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks Bharti. I didn't even see that you were on the email. I accepted some of the non-substance edits at the beginning of the document

---

**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, May 8, 2020 8:54 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks Erica. I saw it in the morning and have sent it for review. I will respond to you as soon as I receive feedback.

Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, May 8, 2020 8:49 AM  
**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Maloney, Diane <Diane.Maloney@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Good morning everyone,

OCC has reviewed the attached letter and included some questions for CBER. Please let me know when your review is complete and I will move the letter up the clearance chain.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
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**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Susan,

Yes, IGA does send items to OP as well.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
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U.S. Food and Drug Administration  
Office: (301)796-8309  
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Congressional and Oversight Branch  
Division of Disclosure and Oversight Management  
CBER/FDA*

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**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

That works. Thanks for letting me know.

Erica

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:23 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

I am hoping to get it to you in next few days.

Thanks,  
Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:21 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks for the update. Do you have an estimated time when it might be done, so I can let FDA Exec Sec know?

Erica

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, April 22, 2020 2:18 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

The response is still under review within CBER. Can we please get an extension?

Thanks,  
Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:11 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Thanks Bharti,

That should be fine. Please keep us posted.

Erica

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:10 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica.

We will try but may need an extension due to other priorities related to COVID-19.

Thanks,  
Bharti

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 2:03 PM  
**To:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Bharti,

If possible, can we receive the cleared final version by COB Wednesday?

Erica

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, April 17, 2020 1:58 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Subject:** FW: inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Erica-

Can you please respond to Bharti? Thanks

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>

**Sent:** Friday, April 17, 2020 1:55 PM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>

**Subject:** inquiry from CA State Senator Weiner ( COB Tracking - C20-212)

Hi Karen.

Hope all is well. You may be aware of the attached inquiry. We are working on it but we do not know what the due date is. Can you please let us know?

Thanks,  
Bharti

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**Sent:** 5/8/2020 10:20:48 AM  
**To:** Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz\_bohn]  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Susan,

I am looking at the answers and want to make sure I understand them correctly. Instead of answering each question individually, The answers are all together at the bottom, correct? Can they be

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Friday, May 8, 2020 9:19 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Thanks for your patience!

---

**From:** White, Erica  
**Sent:** Friday, May 8, 2020 9:19 AM  
**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Thanks everyone.

Erica

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Friday, May 8, 2020 9:13 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,

Here is the response updated to reflect the additional comment that OCC sent late last night. The change is in the paragraph about EUA, "Among these requirements is a determination by the FDA that the known and potential benefits.....". OCC requested that the language state the determination is made by FDA - for accuracy it should not specify by the FDA Commissioner.

Thanks,  
Susan

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**From:** Frantz-Bohn, Susan

**Sent:** Thursday, May 7, 2020 6:15 PM

**To:** White, Erica <Erica.White@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>

**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,

Attached are the responses to questions 2-4. These have been cleared by OCC. Please let me know if you have any questions.

Thanks,

Susan

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**From:** White, Erica

**Sent:** Thursday, April 30, 2020 2:32 PM

**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>

**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Thanks for the update Susan. We look forward to receiving your written responses.

Erica

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>

**Sent:** Thursday, April 30, 2020 2:31 PM

**To:** White, Erica <Erica.White@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>

**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,

CBER would like to provide a written response. Given all that is going on at the moment, we are aiming to have this completed by mid- next week. If changes are made to previously cleared language that was used to draft the response, it may need additional clearances by OCC and the JIC which will require additional time.

Thanks,

Susan

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**From:** White, Erica

**Sent:** Wednesday, April 29, 2020 11:48 AM

**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Thanks Susan. I appreciate the feedback and the suggestions.

Erica



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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>

**Sent:** Wednesday, April 29, 2020 11:08 AM

**To:** White, Erica <Erica.White@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,

Thanks so much for forwarding the questions. I will let you know if CBER decides on a call or written response for Questions 2-4.

The questions listed below are outside of CBER's regulatory scope. I made some suggestions on where you might be able to get responses but you may have other thoughts/ideas:

1. Any federal funding sources for an immunization program for SARS-CoV-2. (suggest CDC respond)
5. Once a vaccine is licensed or otherwise made available for use, how will a priority order for who will receive the vaccine first be established? (suggest HHS/CDC respond)
  - a. By country?
  - b. By profession (e.g. healthcare workers?)
  - c. By region within the United States ("hot spots")?
  - d. Who will decide these issues? The President? FDA and other regulators? WHO?
6. Would the federal government consider ordering people to be vaccinated for SARS-CoV-2? If so, what type of exceptions would you anticipate? (suggest HHS/CDC respond)
7. Not on the topic of vaccines, but any information about whether FDA approved medicines being used to treat COVID-19 patients are being prescribed for off-label use or whether they are being administered as part of a clinical trial for approval for a new indication would be helpful. (CDER should respond)

Thanks,  
Susan

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**From:** White, Erica

**Sent:** Wednesday, April 29, 2020 10:13 AM

**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>

**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Good morning everyone,

The questions from the legislative staffer are in the attached email. Should you decide that a call is warranted, please let me know and I can set one up. I am also happy to send back any written responses, if you prefer to do that instead.

Thank you,

Erica M. White,  
Intergovernmental Affairs  
FDA

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 4:24 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Thanks!

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**From:** White, Erica  
**Sent:** Tuesday, April 28, 2020 4:22 PM  
**To:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Susan,

Thank you for getting back to me. I will follow your suggestions and get a direct contact to see what questions they may have.

Thanks,  
Erica

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**From:** Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>  
**Sent:** Tuesday, April 28, 2020 4:18 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Subject:** FW: Question: FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica,  
I hope all is well with you.

We discussed this request internally. As you know, our staff in our office of vaccines is working non-stop on applications for vaccines to fight COVID-19.

Would you please ask Ms. Nicolson for contact information for the Wisconsin State legislative staffer for so you can request specific questions that are of interest for their publication? We will use those questions to decide if it will be more efficient to have a brief (15 min call) at a pre-arranged time or to respond in writing. We don't have any background but if you feel it is appropriate, you can to provide the following link on the vaccine approval process as an initial resource <https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-product-approval-process>

Thanks,  
Susan

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Monday, April 27, 2020 4:50 PM  
**To:** CBER Exec. Sec. <cber\_execsec@fda.hhs.gov>

**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Good afternoon,

IGA received a request from the National Conference of State Legislatures (NCSL) on behalf of a state legislative staffer to speak with someone at FDA about the biologic vaccine licensure process. The person is working on a publication on vaccine development and immunization for the Wisconsin Legislature. Any assistance you can provide with getting a point of contact for the Wisconsin State legislative staffer would be greatly appreciated.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-3309

Erica.White@fda.hhs.gov



Erica

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**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>

**Sent:** Monday, April 27, 2020 8:43 AM

**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>

**Subject:** Request from Legislative Staff

Good Morning Chris,

We got a request from legislative staff to speak with someone at FDA about the biologic vaccine licensure process. He is working on a publication on vaccine development and immunization for the Wisconsin Legislature. He asked if we could speak to someone this week which I told my colleagues who got this request that might be a stretch with all that is going on. Let me know what you advise and I appreciate any resources you all can share.

Thank You!

Haley Nicholson

National Conference of State Legislatures

Senior Policy Director, Health & Human Services

State-Federal Affairs

202-624-8662 (o)



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**Sent:** 5/11/2020 8:43:22 AM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@gmail.com; emais.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**Subject:** FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients

Good morning,

The FDA Intergovernmental Affairs team would like to bring to your attention that over the weekend, the U.S. Food and Drug Administration issued the first emergency use authorization (EUA) for a COVID-19 antigen test, a new category of tests for use in the ongoing pandemic. These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. The EUA was issued late Friday to Quidel Corporation for the Sofia 2 SARS Antigen FIA. This test is authorized for use in high and moderate complexity laboratories certified by Clinical Laboratory Improvement Amendments (CLIA), as well as for point-of-care testing by facilities operating under a CLIA Certificate of Waiver.

Diagnostic testing is one of the pillars of our nation's response to COVID-19 and the FDA continues to take actions to help make these critical products available, including by issuing EUAs. During this pandemic, there have been two types of tests for which the FDA has issued EUAs. One type are polymerase chain reaction

(PCR) tests, a molecular diagnostic testing technique that detects the genetic material from the virus and can help diagnose an active COVID-19 infection. The other type are serological tests that look for antibodies to the virus, which can help identify individuals who have developed an adaptive immune response to the virus, as part of either an active infection or a prior infection (serological, or antibody, tests should not be used to diagnose active infection).

This latest FDA authorization is for an antigen test, which is a new type of diagnostic test designed for rapid detection of the virus that causes COVID-19. Each category of diagnostic test has its own unique role in the fight against this virus. PCR tests can be incredibly accurate, but running the tests and analyzing the results can take time. One of the main advantages of an antigen test is the speed of the test, which can provide results in minutes. However, antigen tests may not detect all active infections, as they do not work the same way as a PCR test. Antigen tests are very specific for the virus, but are not as sensitive as molecular PCR tests. This means that positive results from antigen tests are highly accurate, but there is a higher chance of false negatives, so negative results do not rule out infection. With this in mind, negative results from an antigen test may need to be confirmed with a PCR test prior to making treatment decisions or to prevent the possible spread of the virus due to a false negative.

Antigen tests are also important in the overall response against COVID-19 as they can generally be produced at a lower cost than PCR tests and once multiple manufacturers enter the market, can potentially scale to test millions of Americans per day due to their simpler design, helping our country better identify infection rates closer to real time.

This is just the first antigen test to be authorized and we expect more to follow. We also anticipate providing an EUA template for antigen tests, similar to ones we've released for other test types, to help manufacturers streamline submissions and help expedite our review and issuance of additional EUAs.

Antigen tests will play a critical role in the fight against COVID-19 and we will continue to offer support and expertise to help with the development of accurate tests, and to review and monitor marketed tests to ensure accuracy, while balancing the urgent need for these critical diagnostics.

For More Information:

FDA: [FAQs on Diagnostic Testing for SARS-CoV-2](#) | FDA

CMS: [Clinical Laboratory Improvement Amendments \(CLIA\)](#)

CDC: [Testing for COVID-19](#)

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 5/11/2020 6:21:05 PM  
**To:** Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.AI]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gome]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: OL Reactive TPs for COVID Briefings  
**Attachments:** Reactive TPs 5.11.20.docx

FYI

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**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Monday, May 11, 2020 5:46 PM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Cc:** Adleberg, Jill <Jill.Adleberg@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Burns, Corey <Corey.Burns@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Feingold, Daniel <Daniel.Feingold@fda.hhs.gov>; George, Bryan <Bryan.George@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Lexer, Susan <Susan.LexerSmith@fda.hhs.gov>; Lockheed, Matthew <Matthew.Lockheed@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Rosebraugh, Sydney <Sydney.Rosebraugh@fda.hhs.gov>  
**Subject:** OL Reactive TPs for COVID Briefings

Attached are OL's Reactive Talking Points, updated through 5pm today.

Thank you.

**Andrew Tantillo, J.D.**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
301-796-8919 M: 202-809-2989  
andrew.tantillo@fda.hhs.gov



**U.S. FOOD & DRUG**  
ADMINISTRATION



---

**Sent:** 5/12/2020 1:38:29 PM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf  
**Attachments:** [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Hi Jennifer,

The Governor of the Commonwealth of the Northern Mariana Islands (CNMI) would like to know if we have any information about the attached test. Any information you can provide would be greatly appreciated.

Also, when we get these types of questions where the test is not listed, is

Erica

---

**From:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
**Sent:** Tuesday, May 12, 2020 12:32 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Baker, Michael G (OS) <Michael.Baker@hhs.gov>  
**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Hi Karen-

(b)(5)

(b)(5)

Thanks, Darcie

Darcie L. Johnston  
Director, Intergovernmental Affairs  
U.S. Department of Health and Human Services  
Office of the Secretary  
202-690-1058 (office)  
(b)(6) (cell)

---

**From:** Jason Osborne <jason@turnberryolutionsllc.com>  
**Sent:** Tuesday, May 12, 2020 11:50 AM  
**To:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
**Subject:** [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Darcie,

Someone in Korea approached the Governor about this product. I can't find them on the list you sent the link for yesterday. How would I check to see if they are allowed? Thanks Jason

Jason Osborne  
202-744-0639

---

**Sent:** 5/12/2020 3:06:51 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

The guidance states they have up to

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, May 12, 2020 3:05 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Looks good. I have not reviewed the guidance in a while. Can the product be sold and used in a lab WHILE it's application is under review?

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Tuesday, May 12, 2020 3:02 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Hi Karen,

Here is a proposed response to CNMI. I checked with Jennifer and she said that there is a preEUA for the kit, but of course we can't share anything about it. I propose sending back our standard email below, with the guidance document and FAQs link at the bottom.

Good afternoon Jason,

Thank you for your email regarding the Biosewoom 2019-nCoV Detection Kit and whether it has received an Emergency Use Authorization (EUA). HHS referred your email to us, FDA Intergovernmental Affairs, for a response. FDA appreciates that you may be receiving many inquiries from medical product developers regarding the status of their submissions for an emergency use authorization (EUA) or approval of products intended to diagnose, treat, or prevent COVID-19. FDA recognizes the urgent nature of these submissions and is reviewing them as quickly as possible, although turnaround times can vary based on the information provided by the applicant. When questions arise or additional information is needed FDA works directly with the developer to keep the review moving. FDA prioritizes those submissions that, based on the information provided, may offer the most impact for the response.

Consistent with our legal and regulatory obligations, and to avoid even the appearance of impropriety during this critical period of product development, the agency is unable to provide status checks or updates on pending applications for anyone other than product sponsors. (In fact, unless a company has made its submission public, FDA cannot even confirm that it has been received, except to the sponsor.) Additionally, this preserves the time of the experts within the review divisions so they can complete reviews and engage with the sponsors more quickly. We thank you for your understanding and commitment to ensuring that FDA review remains the world's gold standard and maintains the highest level of integrity.

If you, or the company, need additional information, including about tests being offered prior to or without an EUA under the policies in the *Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency*, please refer to the FAQs on Diagnostic Testing for SARS-CoV-2.

Hopefully this is helpful. If you have any further questions, please feel free to reach out.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, May 12, 2020 1:49 PM  
**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Cc:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Also, please add inquiry from below: Commonwealth of North Mariana Islands asking about approval of COVID diagnostic test from S. Korea

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**Sent:** Tuesday, May 12, 2020 1:12 PM  
**To:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Meant to copy you for daily.

---

**From:** Meister, Karen G  
**Sent:** Tuesday, May 12, 2020 1:10 PM  
**To:** Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Baker, Michael G (OS) <Michael.Baker@hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Hi Darcie-

Copying Erica who can handle....

Thank you!

Karen

---

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**Sent:** Tuesday, May 12, 2020 12:32 PM  
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**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Hi Karen-

(b)(5)

(b)(5)

Thanks, Darcie

Darcie L. Johnston  
Director, Intergovernmental Affairs

U.S. Department of Health and Human Services

Office of the Secretary

202-690-1058 (office)

(b)(6) (cell)

---

**From:** Jason Osborne <jason@turnberrysolutionsllc.com>

**Sent:** Tuesday, May 12, 2020 11:50 AM

**To:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>

**Subject:** [PCR] Biosewom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

Darcie,

Someone in Korea approached the Governor about this product. I can't find them on the list you sent the link for yesterday. How would I check to see if they are allowed? Thanks Jason

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202-744-0639

---

**Sent:** 5/12/2020 4:00:25 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
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**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Baker, Michael G (OS) <Michael.Baker@hhs.gov>  
**Subject:** FW: [PCR] Biosewoom\_2019-nCoV-Detection-Kit-leaflet-\_english\_.pdf

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(b)(5)

(b)(5)

Thanks, Darcie

Darcie L. Johnston  
Director, Intergovernmental Affairs  
U.S. Department of Health and Human Services  
Office of the Secretary  
202-690-1058 (office)  
(b)(6) (cell)

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Jason Osborne  
202-744-0639

---

**Sent:** 5/13/2020 8:54:13 AM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** scott.harris@adph.state.al.us; patricia.vinson@adph.state.al.us; lily.lou@alaska.gov; tuinua@doh.as; euiagalelei@doh.as; cara.christ@azdhs.gov; wendy.snyder@azdhs.gov; nathaniel.smith@arkansas.gov; reva.ferguson@arkansas.gov; susan.fanelli@cdph.ca.gov; peggy.ullom@cdph.ca.gov; jill.hunsakerryan@state.co.us; esther.muna@dph.gov.mp; janet.guerrero@dph.gov.mp; renee.coleman-mitchell@ct.gov; dana.jensen@ct.gov; karyl.rattay@state.de.us; richard.little@state.de.us; nathan.maccormack@state.de.us; laquandra.nesbitt@dc.gov; monique.johnson@dc.gov; scott.rivkees@flhealth.gov; summer.bane@flhealth.gov; kathleen.toomey@dph.ga.gov; fanny.vazquez@dph.ga.gov; linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; shawe@dhw.idaho.gov; ngozi.ezike@illinois.gov; shirley.musgrave@illinois.gov; kbox@isdh.in.gov; tbarrett@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; jennifer.caskey@idph.iowa.gov; caitlin.pedati@idph.iowa.gov; lee.norman@ks.gov; steven.stack@ky.gov; deb.colston@ky.gov; alexander.billiou@la.gov; peggy.lantrip@la.gov; nirav.shah@maine.gov; peggie.d.lawrence@maine.gov; fran.phillips@maryland.gov; dionne.washington@maryland.gov; monica.bharel@state.ma.us; renee.walsh@state.ma.us; reidc2@michigan.gov; andersonp3@michigan.gov; jan.malcolm@state.mn.us; sandy.pizzuti@state.mn.us; thomas.dobbs@msdh.ms.gov; jenny.griffin@msdh.state.ms.us; randall.williams@health.mo.gov; debbie.mebruer@health.mo.gov; sheilahogan@mt.gov; bo.botelho@nebraska.gov; bhandler@health.nv.gov; lisa.morris@dhhs.nh.gov; kelly.bogert@dhhs.nh.gov; shereef.elnahal@doh.nj.gov; kathy.kunkel@state.nm.us; howard.zucker@health.ny.gov; jacki.silvia-fink@health.ny.gov; danny.staley@dhhs.nc.gov; holly.murray@dhhs.nc.gov; mylynntufte@nd.gov; lrodahl@nd.gov; lance.himes@odh.ohio.gov; garyc@health.ok.gov; mdianeh@health.ok.gov; lillian.shirley@dshsoha.state.or.us; patricia.nest@dshsoha.state.or.us; ralevine@pa.gov; tbarnett@pa.gov; bcaboot@pa.gov; rreveron@salud.pr.gov; nicole.alexanderscott@health.ri.gov; rita.menard@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; monica.harding@state.sd.us; lisa.piercey@tn.gov; tammy.stanton2@tn.gov; john.hellerstedt@dshs.texas.gov; joeminer@utah.gov; mark.levine@vermont.gov; sarah.gregorek@vermont.gov; michelle.davis@doh.vi.gov; norbin.felix@doh.vi.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; terry.bergener@doh.wa.gov; rahul.gupta@wv.gov; andrea.l.fisher@wv.gov; charles.warzecha@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** FDA Hotline Information

Good morning,

FDA's Intergovernmental Affairs staff would like to flag that FDA's hotline (1-888-INFO-FDA) is available 24 hours a day for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs, media needed for transport, and conservation of the samples. We also encourage labs to reach out at [CDRH-EUA-Templates@fda.hhs.gov](mailto:CDRH-EUA-Templates@fda.hhs.gov) with any questions related to diagnostic development. We hope this will be useful to your constituent developers.

You may also be interested in our COVID-19 Frequently Asked Questions page, which contains information on vaccines, diagnostic tests, drugs, medical devices, food and other products FDA regulates.

Thank you and please don't hesitate to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) if you have any questions or need information as this situation develops.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)





**Sent:** 5/14/2020 8:01:14 PM

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**Subject:** FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test

Good evening,

FDA's Intergovernmental Affairs wanted to bring to your attention that, today, the U.S. Food and Drug Administration is alerting the public to early data that suggest potential inaccurate results from using the Abbott ID NOW point-of-care test to diagnose COVID-19. Specifically, the test may return false negative results.

"We are still evaluating the information about inaccurate results and are in direct communications with Abbott about this important issue. We will continue to study the data available and are working with the company to create additional mechanisms for studying the test. This test can still be used and can correctly identify many positive cases in minutes. Negative results may need to be confirmed with a high-sensitivity authorized molecular test," said Tim Stenzel, M.D., Ph.D., director of the Office of In Vitro Diagnostics and Radiological Health in the FDA's Center for Devices and Radiological Health.

The FDA is sharing early information available about potential inaccurate results in the spirit of transparency. The agency has been working with Abbott to analyze the information gathered to date and has worked with the company on a customer notification letter to alert users that any negative test results that are not consistent with a patient's clinical signs and symptoms or necessary for patient management should be confirmed with another test.

The FDA looks at a variety of sources to identify and understand potential patterns or significant issues with the use of the Abbott test. No diagnostic test will be 100% accurate due to performance characteristics, specimen handling, or user error, which is why it is important to study patterns and identify the cause of suspected false results so any significant issues can be addressed quickly.

The agency is aware of some scientific studies that have identified accuracy issues with Abbott ID NOW and is investigating whether it could be due to the types of swabs used or the type of viral transport media (material used to transport the patient's specimen). While there is important information to gather from these studies, it should be noted these studies have limitations, including small sample size, potential design biases, or tests that may not have been executed according to the manufacturer's instructions for use, an important part of scientific research. This is why external scientific studies are one part of the FDA's overall evaluation of a diagnostic performance.

The FDA has received 15 adverse event reports about the Abbott ID NOW device that suggest some users are receiving inaccurate negative results. The agency is reviewing these reports. It's important to note that the adverse event reports the FDA receives from manufacturers, health care providers, health care facilities, and patients can be incomplete, inaccurate, or unverified, so agency staff must meticulously comb through the reports to identify crucial data to support any signals or patterns about device use.

Moving forward, Abbott has agreed to conduct post-market studies for the ID NOW device that each will include at least 150 COVID-19 positive patients in a variety of clinical settings. The FDA will continue to review interim data on an ongoing basis. The information gathered from the post-market studies can further help the agency understand the cause or patterns of any accuracy issues and inform any additional actions the company or the FDA should take.

The FDA will keep working with Abbott to further evaluate these accuracy issues and will publicly communicate any updates.

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**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
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The FDA will keep working with Abbott to further evaluate these accuracy issues and will publicly communicate any updates.

Consumers or healthcare providers can reach Abbott directly at (224) 667-6100 or by email.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
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**Subject:** Coronavirus (COVID-19) Update: Daily Roundup May 14, 2020

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:

- The FDA issued an Emergency Use Authorization (EUA) for infusion pumps and infusion pump accessories that, among other things, meet certain safety, performance, and labeling criteria, in response to concerns relating to the insufficient supply and availability of the devices for use by healthcare providers in the continuous infusion of medications, total parenteral nutrition, and/or other fluids into patients during the COVID-19 pandemic. This includes infusion pumps with remote monitoring or remote manual control features or administration sets and other accessories with increased length that help to maintain a safe physical distance between healthcare providers and patients with or suspected of having COVID-19 to reduce healthcare provider exposure. Infusion pumps and accessories that have been confirmed by FDA to meet the criteria will be added to the letter of authorization in Appendix A. A manufacturer may request the addition of any eligible infusion pump and/or infusion pump accessory to Appendix A by submitting a request to [CDRH-COVID19-InfusionPumps@fda.hhs.gov](mailto:CDRH-COVID19-InfusionPumps@fda.hhs.gov), as outlined in the EUA.
- Today, the FDA issued an update to its guidance for pharmacy compounders that experience shortages of the personal protective equipment (PPE) they typically use to compound human drugs that are intended or expected to be sterile. In the update, FDA has clarified that drugs can be compounded under the policy in a segregated compounding area that is not in a cleanroom, when specific beyond-use dates are utilized. FDA adopted this policy to help assure patient access to needed medicines and to reduce the risks of compounding when standard PPE are not available.
- **Testing updates:**
  - During the COVID-19 pandemic, the FDA has worked with more than 390 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus.
  - To date, the FDA has authorized 98 tests under EUAs, which include 85 molecular tests, 12 antibody tests, and 1 antigen test.

#### **Additional Resources:**

- [Coronavirus Disease 2019 \(COVID-19\)](#)

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- Testing updates:
  - During the COVID-19 pandemic, the FDA has worked with more than 390 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus.
  - To date, the FDA has authorized 98 tests under EUAs, which include 85 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

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**Sent:** 5/15/2020 9:54:26 AM  
**Subject:** FW: urgent question on state EUAs

Hi Erica,

Please provide the following to HHS for the WA Governor's office (this is the response we cleared for the press). Please also let them know we reached out to UWA on Wednesday evening and are continuing to work with them on their options.

Best,

Jennifer

FDA's recommendations for COVID-19 testing on the use of at-home testing, including at-home specimen collection have not changed. The FDA's guidance has provided a Policy for Coronavirus Disease-2019 Tests, which does not apply to home collection of specimens to be sent for testing at a laboratory certified under CLIA for high-complexity testing. The recent guidance updates did not change the policy regarding state oversight. Home collection raises additional concerns about safety and accuracy that require FDA review, as we have discussed in our FAQs and other communications about home collection.

Research studies conducted under supervision of an Institutional Review Board (IRB) are handled separately, and in such case, an IRB may determine that home collection may occur with appropriate mitigations under such a supervised study.

We had previously understood that SCAN was being conducted as a surveillance study. As appropriately determined by the applicable IRB, such an option for home collection may be available to the project sponsors.

**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>

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**From:** White, Erica <Erica.White@fda.hhs.gov>

**Sent:** Wednesday, May 13, 2020 4:25 PM

**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** FW: urgent question on state EUAs



Hi Jennifer,

Please see the question below from Washington State Governor on whether it was FDA's intent to halt home testing under state-issued EUAs in addition to those with pending EUA applications. The state also wants to know whether it is FDA's intent to halt the state's authority to issue EUAs. Any assistance you can provide with an answer would be greatly appreciated.

Erica

---

**From:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
**Sent:** Wednesday, May 13, 2020 4:19 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
**Subject:** FW: urgent question on state EUAs

Hi Karen and Erica-

Please see below on question from Washington State Gov office. Thanks, Darcie

Darcie L. Johnston  
Director, Intergovernmental Affairs  
U.S. Department of Health and Human Services  
Office of the Secretary  
202-690-1058 (office)  
(b)(6) cell)

---

**From:** Katims, Casey (GOV) <casey.katims@gov.wa.gov>  
**Sent:** Wednesday, May 13, 2020 3:56 PM  
**To:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
**Cc:** Wilson, Morgan (GOV) <Morgan.Wilson@gov.wa.gov>  
**Subject:** urgent question on state EUAs

Darcie:

As I mentioned by phone, the Greater Seattle Coronavirus Assessment Network (SCAN) has been operating under a state-issued EUA for its community surveillance partnership with Seattle-King County Public Health since early March, but in parallel submitted an EUA application to the FDA on March 23rd. They have been using at-home collection kits for this study.

Pursuant to FDA's changes requiring an approved EUA for home testing, they have been forced to pause their work.

**Can you confirm whether it was FDA's intent to halt home testing under state-issued EUAs in addition to those with pending EUA applications? Is it also FDA's intent to halt the state's authority to issue EUAs?**

Thanks for any help. Our folks are confused and would appreciate any clarity. They are also eager to get the SCAN efforts back up and running.

Casey

360.999.0155

---

**From:** Jay Shendure <shendure@uw.edu>  
**Sent:** Tuesday, May 12, 2020 10:49:33 PM  
**To:** Lindquist, Scott W (DOH) <scott.lindquist@doh.wa.gov>; Estes, Honora L (DOH) <honora.estes@doh.wa.gov>; kristin.peterson@doh.wa.gov <kristin.peterson@doh.wa.gov>  
**Cc:** Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Christina M Lockwood <tinalock@uw.edu>; Apa, James <James.Apa@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Mark Rieder <mrieder@uw.edu>  
**Subject:** important SCAN updates

[EXTERNAL Email Notice! ] External communication is important to us. Be cautious of phishing attempts. Do not click or open suspicious links or attachments.

Dear Honora, Scott and Kristin --

I am writing on behalf of the SCAN team to let you know about some important developments that occurred earlier today. As you know, the [REDACTED] (b)(4) [REDACTED] for SCAN has been operating under a WA-issued EUA for our community surveillance partnership with PHSKC since early March, but in parallel submitted an EUA application to the FDA on March 23rd. We have been in regular communication with the FDA about our study since before that EUA submission and the ensuing 2 months.

We were notified this morning that consequent to changes in the FDA's EUA guidance around home testing that were made last Friday (5/8), returning SARS-CoV-2 results to patients using at-home collection kits is no longer allowed without an authorized EUA, i.e. while the EUA application is under consideration. We were therefore asked to discontinue testing through SCAN until the EUA has successfully been obtained.

We have of course complied and paused testing today, and I have copied below a draft of a public-facing message that will be posted at the SCAN website in the morning, together with relevant Q&A. We are unclear how this new guidance intersects with our WA EUA or the state's authority to issue EUAs. The timing here is really unfortunate, as we've just begun to aggressively scale SCAN's facilitation of testing of individuals identified through contact tracing in collaboration with PHSKC, as well as to pivot towards targeted testing of high-risk communities and essential workers.

We would welcome the opportunity to discuss these developments with you in the next day or two if we can arrange it. I have cc'd Jeff Duchin and several of his colleagues at PHSKC, as well as Tina Lockwood (our lab director) and Mark Rieder (SCAN's program director).

Best regards,

Jay Shendure

\*\*\*\*\*

#### **SCAN Statement**

*SCAN has been operating under an emergency use authorization (EUA) from the Washington State Department of Health. On March 16<sup>th</sup>, the Food & Drug Administration (FDA) granted states authority to issue EUAs for tests developed and used by laboratories within their states. However, we have been notified that under revised guidance issued on May 8<sup>th</sup>, a separate federal EUA is now required to return results.*

*We have been in conversation with the FDA since March 1<sup>st</sup> and hope to have our EUA soon. We notified the agency about our lab-developed test and self-swab kit on March 23<sup>rd</sup> and, in accordance with the*

*EUA process and timeline, submitted data to secure federal authorization on April 13<sup>th</sup>. We are actively working to address their questions.*

*We're pleased to see that the agency's recent guidance now includes provisions for home-based self-collection of diagnostic samples in specific circumstances. This paves the way for continued progress in expanding access to safe, reliable, convenient, and scalable testing options.*

*We are grateful for productive partnerships with the FDA, the Washington State Department of Health, and the Centers for Disease Control and Prevention as we continue to respond to this unprecedented and rapidly changing outbreak.*

## **Frequently Asked Questions**

**Q:**

**What data have you submitted to the FDA?**

**A:**

The agency has requested data regarding SCAN's use of mid-turbinate nasal swabs. We have submitted data validating the safety of these swabs for home-based collection, as well as the reliability of our lab-developed test for specimens collected using our self-swab kits.

We have performed internal studies to determine shipping and specimen stability with our assay, testing approximately 17,000 home-collected mid-turbinate swabs from both adults and children—including Seattle Flu Study and SCAN samples. We have provided the following information to the FDA:

- To date, only a single, minor adverse event has been reported.
- Our shipping and stability studies have established that detection of SARS-CoV-2 is stable for over a week at high and low regional temperatures.
- With regard to proper specimen collection outside of a clinical setting, our experience from more than 18 months of sampling with the Seattle Flu Study and now SCAN also shows a low rate of insufficient nasal sampling. The internal control in our assay readily identifies whether a sufficient specimen is collected.

Numerous scientific studies have established similar rates of detection for mid-turbinate swabs and the nasal pharyngeal swabs typically used in clinical testing, including for SARS-CoV-2 detection. The Infectious Diseases Society of America (IDSA) guidelines endorse the use of mid-turbinate swabs and reference the potential for self-collection with appropriate instructions.

Page

Break

**Q:**

**What other questions has the FDA raised?**

**A:**

We have been asked about our testing of people who have not reported COVID-like illness (CLI). Since community sampling began on March 23, SCAN has tested 7,106 samples from respondents with self-reported COVID-like illness (CLI) and 5,376 samples from respondents not reporting CLI symptoms.

It has been established that COVID-19 can spread even among those who are asymptomatic. It's important that SCAN collects data on the pathogen both from people who feel sick enough to seek care (but are not suspected of having COVID-19) as well as those not seeking care, who are mildly ill or not ill at all. This can not only help us learn more about the virus, it can help us identify positive cases of COVID-19 that might otherwise go undetected.

**Q:**

**I'm currently enrolled in the SFS household study. Has that been paused?**

**A:**

The household study relies on home-based self-collection and therefore has also been paused. We hope to be able to resume testing soon.

**Q:**

**Are you also pausing your testing in homeless shelters and long-term care facilities?**

**A:**

Our work in homeless shelters and long-term care facilities continues. These are separate research studies under the banner of the Seattle Flu Study. Samples are collected under the supervision of a health care worker and do not involve home-based self-collection.

\*\*\*\*\*

-----  
Jay Shendure, MD, PhD  
Investigator, Howard Hughes Medical Institute  
Director, Allen Discovery Center for Lineage Tracing  
Director, Brotman Baty Institute for Precision Medicine  
Professor, Genome Sciences, University of Washington  
shendure@uw.edu | 206.685.8543  
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**Sent:** 5/15/2020 10:25:21 AM  
**Subject:** FW: urgent question on state EUAs

Good morning Casey,

Thank you for your email below regarding the SCAN state-issued EUA. HHS referred your email to us, FDA Intergovernmental Affairs, for a response. FDA's recommendations for COVID-19 testing on the use of at-home testing, including at-home specimen collection have not changed. The FDA's guidance has provided a Policy for Coronavirus Disease-2019 Tests, which does not apply to home collection of specimens to be sent for testing at a laboratory certified under CLIA for high-complexity testing. The recent guidance updates did not change the policy regarding state oversight. Home collection raises additional concerns about safety and accuracy that require FDA review, as we have discussed in our FAQs and other communications about home collection.

Research studies conducted under supervision of an Institutional Review Board (IRB) are handled separately, and in such case, an IRB may determine that home collection may occur with appropriate mitigations under such a supervised study.

We had previously understood that SCAN was being conducted as a surveillance study. As appropriately determined by the applicable IRB, such an option for home collection may be available to the project sponsors.

I also wanted to let you know that FDA reached out to (b)(4) and is continuing to work with them on their options.

If you have additional questions please feel free to contact me.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Katims, Casey (GOV) <casey.katims@gov.wa.gov>  
**Sent:** Wednesday, May 13, 2020 3:56 PM  
**To:** Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>  
**Cc:** Wilson, Morgan (GOV) <Morgan.Wilson@gov.wa.gov>  
**Subject:** urgent question on state EUAs

Darcie:

As I mentioned by phone, the Greater Seattle Coronavirus Assessment Network (SCAN) has been operating under a state-issued EUA for its community surveillance partnership with Seattle-King County Public Health since early March, but in parallel submitted an EUA application to the FDA on March 23rd. They have been using at-home collection kits for this study.

Pursuant to FDA's changes requiring an approved EUA for home testing, they have been forced to pause their work.

**Can you confirm whether it was FDA's intent to halt home testing under state-issued EUAs in addition to those with pending EUA applications? Is it also FDA's intent to halt the state's authority to issue EUAs?**

Thanks for any help. Our folks are confused and would appreciate any clarity. They are also eager to get the SCAN efforts back up and running.

Casey

360.999.0155

---

**From:** Jay Shendure <shendure@uw.edu>  
**Sent:** Tuesday, May 12, 2020 10:49:33 PM  
**To:** Lindquist, Scott W (DOH) <scott.lindquist@doh.wa.gov>; Estes, Honora L (DOH) <honora.estes@doh.wa.gov>; kristin.peterson@doh.wa.gov <kristin.peterson@doh.wa.gov>  
**Cc:** Duchin, Jeff <Jeff.Duchin@kingcounty.gov>; Christina M Lockwood <tinalock@uw.edu>; Apa, James <James.Apa@kingcounty.gov>; Cowgill, Karen <n-kcowgill@kingcounty.gov>; Mark Rieder <mrieder@uw.edu>  
**Subject:** important SCAN updates

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Dear Honora, Scott and Kristin --

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Best regards,

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\*\*\*\*\*

## SCAN Statement

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## Frequently Asked Questions

**Q:**

**What data have you submitted to the FDA?**

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Page

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**Q:**

**Are you also pausing your testing in homeless shelters and long-term care facilities?**

**A:**

Our work in homeless shelters and long-term care facilities continues. These are separate research studies under the banner of the Seattle Flu Study. Samples are collected under the supervision of a health care worker and do not involve home-based self-collection.

\*\*\*\*\*

-----  
Jay Shendure, MD, PhD  
Investigator, Howard Hughes Medical Institute  
Director, Allen Discovery Center for Lineage Tracing  
Director, Brotman Baty Institute for Precision Medicine  
Professor, Genome Sciences, University of Washington  
shendure@uw.edu | 206.685.8543  
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**Sent:** 5/15/2020 11:12:21 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: COVID Immunity Testing

Hi Karen,

This is the same person from Senator Brian Kelsey's office that you spoke with a little while ago.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Friday, May 15, 2020 10:32 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: COVID Immunity Testing

Hi Erica and Karen,

Can you follow up with staff for the state senate office below: (b)(5)

(b)(5)

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:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>  
**Sent:** Friday, May 15, 2020 10:23 AM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Lovell, Stephen <Stephen.Lovell@fda.hhs.gov>  
**Subject:** FW: COVID Immunity Testing

Jennifer,

FYI, we just got this inquiry regarding EUA authorization. It appears to be from a staff member for TN state senator Brian Kelsey. Did you want to respond or did you want us to respond?

Leroy

---

**From:** Jennifer Martinez <jennifer@briankelsey.org>  
**Sent:** Friday, May 15, 2020 10:18 AM  
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Lovell, Stephen <Stephen.Lovell@fda.hhs.gov>  
**Cc:** CDRH-EUA-Templates; (b)(6)  
**Subject:** Re: COVID Immunity Testing

We are inquiring to see if th (b)(4) (see attached) has been granted EUA authorization? Have they been found to be reliable?

Thank you in advance for your assistance.

Jennifer Martinez  
District Representative  
Senator Brian Kelsey  
901-239-4601



Submission Number: (b)(4)  
Received: 3/25/2020  
Applicant: (b)(4)  
Device (b)(4)

---

**Sent:** 5/15/2020 11:44:33 AM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**Subject:** RE: COVID Immunity Testing

Good afternoon Ms. Martinez,

Thank you for your email below regarding whether the Genrui BioTech Novel Coronavirus IgG/IgM Test has been granted EUA authorization and whether it's reliable. FDA's Center for Devices and Radiological Health (CDRH) referred your email to us, Intergovernmental Affairs, for a response. This test has not been authorized by FDA but the manufacturer did notify FDA that it is offering the test. Laboratories and manufacturers that have so notified FDA are listed on FDA's website, <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2>. Manufacturers are also required to submit an EUA within 10 business days as set out in our guidance *Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff: Policy for Coronavirus Disease-2019 Tests during the Public Health Emergency (Revised)*

FDA's policy set forth in the guidance states: "FDA does not intend to object to a commercial manufacturer's development and distribution of serology tests to identify antibodies to SARS-CoV-2 for a reasonable period of time, where the test has been validated and while the manufacturer is preparing its EUA request, where the manufacturer gives notification of validation to FDA as described in subsection D.2 below, and

Hopefully this is helpful. If you have additional questions, please feel free to reach out.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, May 15, 2020 11:37 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: COVID Immunity Testing

Would you mind trying? If you aren't able to handle by the time I get back (12:30 when I have a call), I will call her. Thanks.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, May 15, 2020 11:36 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: COVID Immunity Testing

This is actually the same person from Senator Brian Kelsey's office that you spoke with a little while ago. You may actually

(b)(5)

(b)(5)

---

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**Sent:** Friday, May 15, 2020 11:34 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: COVID Immunity Testing

Able to handle? Good email to Casey. Thank you!

---

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**Sent:** Friday, May 15, 2020 10:32 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: COVID Immunity Testing

Hi Erica and Karen,

Can you follow up with staff for the state senate office below who contacted us about an immunity test? It looks like this developer has notified us that they validated the test and are offering it: <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/fags-testing-sars-cov-2>. The test is not authorized yet, but is required to submit an EUA under the updated serology policy. If the test is authorized, it will be listed on our website along with the others.

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>

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**From:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>  
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Leroy

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**Sent:** Friday, May 15, 2020 10:18 AM  
**To:** Hwang, Leroy <Leroy.Hwang@fda.hhs.gov>; Lovell, Stephen <Stephen.Lovell@fda.hhs.gov>

Cc: CDRH-EUA-Templates <COVID19DX@fda.hhs.gov>

Subject: Re: COVID Immunity Testing

We are inquiring to see if the (b)(4) (see attached) has been granted EUA authorization? Have they been found to be reliable?

Thank you in advance for your assistance.

Jennifer Martinez  
District Representative  
Senator Brian Kelsey  
901-239-4601



Submission Number (b)(4)

Received: 3/25/2020

Applicant (b)(4)

Device: Novel (b)(4)

---

**From:** Erica.White@fda.hhs.gov [Erica.White@fda.hhs.gov]  
**Sent:** 5/18/2020 8:53:58 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** Fwd: Coronavirus (COVID-19) Update: Daily Roundup

## FOR IMMEDIATE RELEASE

May 18, 2020

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:

- The FDA issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
  - The first seller warned, Noetic Nutraceuticals, offers CBD products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19.
  - The second seller warned, The Golden Road Kratom, offers kratom products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19.
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- Testing updates:

- During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus.
- To date, the FDA has authorized 103 tests under EUAs, which include 90 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- Coronavirus Disease 2019 (COVID-19)

###

**Media Contact:** Molly.Block@fda.hhs.gov, 240-701-7422

**Consumer Inquiries:** 888-INFO-FDA

*The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

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**Sent:** 5/18/2020 9:37:07 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup May 18, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:



- The FDA issued warning letters to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
  - The first seller warned, Noetic Nutraceuticals, offers CBD products for sale in the U.S. with misleading claims that the products are safe and/or effective for the prevention and treatment of COVID-19.
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- Testing updates:
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  - To date, the FDA has authorized 103 tests under EUAs, which include 90 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- Coronavirus Disease 2019 (COVID-19).

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**From:** Rosebraugh, Sydney [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=21EEBB94E1F34DDCBC1334ACC9CA4E82-SYDNEY.ROSE]  
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**CC:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gome]; Luebke, Yasemin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]  
**Subject:** FEMA Q&A Summaries 5/19

### **Region V (IL, IN, MI, MN, OH, WI)**

Rep. Schneider (IL) asked if Illinois was catching up and ahead of the curve for an impending spike in fall (in terms of equipment). FEMA advised that the supply chain is catching up in terms of the ramping up of PPE production, awareness of the public, alternate care sites, and better ability to track data.

A staffer for a WI representative stated that WI only has 10 days' worth of gowns left and asked for the status of their outstanding request; she also asked who will fill their request for reagents for testing if FEMA cannot. FEMA advised that there is a new gown shortage as gown manufacturers shifted their attention to masks; they have no update on the request. FEMA advises that state labs should acquire test materials through the IRR process and that private labs must acquire them through traditional vendors.

A staffer asked if the president is restructuring the SNS resources. FEMA advised that this is an HHS issue and they will take this question as a getback.

A staffer asked if the state determines who needs PPE. FEMA advised that the state decides allocation of commodities in the states with priority for medical and healthcare community.

A staffer for Sen. Stabenow (MI) asked why Title 32 only extends through June 24<sup>th</sup> when before it was at the end of the month. FEMA advised they have no explanation at this time, but that it might be explained by the fact that a period of quarantine had been requested for the guard before returning home.

### **New Jersey (Jill covered)**

Reps. Norcross and Pallone both expressed concern that while the situation in the northern part of the state is improving, southern New Jersey may need additional resources now.

Rep. Pallone asked how FEMA is prioritizing PPE now that hospitals are restarting elective surgeries – and asked for comment on his concern that there isn't a systematic plan for testing workers. FEMA responded to the first issue noting that it's still prioritizing based on immediate COVID needs – and focusing on nursing homes and long-term care facilities. They didn't really answer the second question.

Several Members asked about the National Guard. FEMA is working to extend their stay for another month 'til mid-July. Members were pleased – and offered to provide any support.

Rep. Pallone asked about contact tracing. FEMA responded that the Governor is trying to hire a few hundred people to work in their communities.

## Oregon

Aaron (House Committee on Transportation and Infrastructure) stated that on a call with governors, the White House announced that corona relief funds can be used for Stafford act assistance – has the state received any guidance on that? FEMA advised that they have no received anything official beyond the informal discussion between the president and the governors. Aaron also asked that, as testing was ramping up, if there are any other shortfalls for the state at this time. FEMA advised that testing supplies are still short, so they are being triaged and prioritized; however, they are hiring contact tracers ahead of the governor's reopening plan.

### **Sydney Rosebraugh, MS**

*Congressional Affairs Specialist*

**Office of Legislation**

**U.S. Food and Drug Administration**

Office: (240) 402-2305

[sydney.rosebraugh@fda.hhs.gov](mailto:sydney.rosebraugh@fda.hhs.gov)



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**Sent:** 5/21/2020 6:59:42 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup May 21, 2020

Good afternoon,

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:

- Today, the FDA posted a list of antibody tests that are being removed from the "notification list" of tests being offered under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. Antibody tests on this new removal list include those voluntarily withdrawn from the notification list by the test's commercial manufacturer and those for which there is not a pending Emergency Use Authorization (EUA) request or issued EUA. The FDA expects that the tests on the removal list will not be marketed or distributed. Antibody tests offered by commercial manufacturers as outlined under the policy, which was issued on March 16 and updated on May 4, continue to be located on the notification list pending review of their EUA request.
- The FDA issued the guidance "Supplements for Approved Premarket Approval (PMA) or Humanitarian Device Exemption (HDE) Submissions During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency" to help foster the continued availability of medical devices during the COVID-19 public health emergency. As described in the guidance, the FDA does not intend to object to limited modifications to the design and manufacturing of devices approved through either a PMA or HDE without prior submission of a PMA or HDE supplement or 30-day notice for the duration of the public health emergency. The policy set forth in the guidance does not apply to design or manufacturing changes made for reasons other than addressing manufacturing limitations or supply chain issues resulting from the COVID-19 public health emergency or to any proposed changes described in a regulatory submission already received by FDA.
- The FDA approved two abbreviated new drug applications:
  - Dexmedetomidine hydrochloride in 0.9% sodium chloride injection, is indicated for sedation of initially intubated and mechanically ventilated patients during treatment in an intensive care setting and sedation of non-intubated patients prior to and/or during surgical and other procedures. The most common side effects of dexmedetomidine hydrochloride injection are hypotension, bradycardia, and dry mouth. This drug is listed in the FDA Drug Shortage Database.
  - Succinylcholine chloride injection USP 200 mg/10 mL, is indicated in addition to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Side effects of succinylcholine chloride injection include anaphylaxis, hyperkalemia, and malignant hyperthermia.
  - The FDA recognizes the increased demand for certain products during the COVID-19 public health emergency, and we remain deeply committed to facilitating access to medical products to help address critical needs of the American public.
- Due to the COVID-19 pandemic and its impacts, earlier this month the U.S. District Court for the Eastern District of Texas granted a joint motion in the case of R.J. Reynolds Tobacco Co. et al. v. U.S. Food and Drug Administration et al. to govern proceedings in that case and postpone the effective date of the "Required Warnings for Cigarette Packages and Advertisements" final rule by 120 days. The new effective date of the final rule is Oct. 16, 2021. The FDA intends to update its relevant guidances related to the rule's effective date and the timing for submission of cigarette plans.
- Testing updates:

- During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus.
- To date, the FDA has authorized 105 tests under EUAs, which include 92 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**Sent:** 5/22/2020 4:50:46 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup May 22, 2020

## Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response effort to the COVID-19 pandemic:

- Today, FDA and the U.S. Department of Agriculture released recommendations to help address shortages of personal protective equipment (PPE), cloth face coverings, disinfectants, and sanitation supplies in the food and agriculture industry during the COVID-19 pandemic.
- The FDA issued an updated [FDA COVID-19 Response At-A-Glance Summary](#) that provides a quick look at facts, figures and highlights of the agency's response efforts.
- The FDA issued a guidance document to provide additional temporary flexibility in food labeling requirements to manufacturers and vending machine operators. The agency is providing flexibility for manufacturers to make minor formulation changes in certain circumstances without making conforming label changes. Also, the FDA is providing temporary flexibility to the vending machine industry and will not object if covered operators do not meet vending machine labeling requirements to provide calorie information for foods sold in the vending machines at this time.
- In a new video, [Donate Blood and Plasma to Make a Difference](#), the FDA explains one way you can make a difference is to donate blood or plasma if you are eligible to donate.
- The FDA and the Federal Trade Commission issued a warning letter to two companies for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
  - The first seller warned, [Apollo Holding LLC](#), offers "NoronaPak" products, including cannabidiol (CBD) and other supplement products for sale in the U.S. with claims that misleadingly represent the products as safe and/or effective for the prevention and treatment of COVID-19.
  - The second seller warned, [North Coast Biologics LLC](#), has offered the unapproved "nCoV19 spike protein vaccine" for sale in the U.S. with misleading claims that the product is safe and/or effective for the prevention of COVID-19.
- The FDA updated the [FAQs on Testing for SARS-CoV-2](#) to clarify information about at-home self-collection and what tests should no longer be distributed for COVID-19.
  - Test developers can offer their COVID-19 tests for at-home self-collection of a specimen if at-home self-collection of a specimen is specifically authorized under the Emergency Use Authorization (EUA) for the test. In addition, COVID-19 tests for at-home self-collection may be used as part of an Institutional Review Board-approved study. The FDA is supportive of at-home self-collection and has authorized several COVID-19 tests for home collection of specimens to be sent to a laboratory for processing and test reporting.
  - The FDA added a new section to the [FAQs](#) to clarify what tests should no longer be distributed for COVID-19. Yesterday, the FDA posted a list of commercial manufacturers' antibody tests that have been removed from the "notification list" of tests being offered under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. Antibody tests on this new removal list include those voluntarily withdrawn from the notification list by the test's commercial manufacturer and those for which there is not a pending EUA request or issued EUA. FDA expects that the tests on the removal list will not be distributed.
- Testing updates:

- During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus.
- To date, the FDA has authorized 109 tests under EUAs, which include 96 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

**Media Contact:** [Molly.Block@fda.hhs.gov](mailto:Molly.Block@fda.hhs.gov), 240-701-7422

**Consumer Inquiries:** 888-INFO-FDA

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**Sent:** 5/24/2020 1:52:21 PM  
**Subject:** FW: [EXTERNAL] Question

Good afternoon Maribel,

Thank you for your email requesting “any guidance on using anesthesia equipment, in place of a ventilator in response to COVID-19”. FDA plays a critical role in protecting the United States from threats including emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic. FDA is issued this guidance to provide a policy to help expand the availability of ventilators as well as other respiratory devices and their accessories during this pandemic. This policy is intended to remain in effect only for the duration of the public health emergency related to COVID-19 declared by the Department of Health and Human Services (HHS), including any renewals made by the Secretary in accordance with section 319(a)(2) of the PHS Act. FDA’s guidance on ventilators can be found at the following website:

<https://www.fda.gov/media/136318/download>.

FDA welcomes the opportunity to work with manufacturers not previously engaged in medical device manufacturing with the interest and capability to manufacture ventilatory support devices. This may include US manufacturers in other manufacturing sectors. These manufacturers should send an email to [CDRH-COVID19-Ventilators@fda.hhs.gov](mailto:CDRH-COVID19-Ventilators@fda.hhs.gov) and describe their proposed approach. FDA intends to work collaboratively with these manufacturers through its EUA process.

We hope this information is helpful to you.

For general FDA-related inquiries, please feel free to contact FDA’s IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) .

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** Ramos, Maribel <[MRamos@nga.org](mailto:MRamos@nga.org)>  
**Sent:** Tuesday, March 24, 2020 3:20 PM  
**To:** Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>; Alexander, Nicholas <[Nicholas.Alexander@fda.hhs.gov](mailto:Nicholas.Alexander@fda.hhs.gov)>; Campbell, Christopher <[Christopher.Campbell@fda.hhs.gov](mailto:Christopher.Campbell@fda.hhs.gov)>  
**Subject:** Question

Hello all,



I hope you all are doing ok. I am writing to ask if FDA has sent out any guidance on using anesthesia equipment, in place of a ventilator in response to COVID-19?

Thanks for any help!

Maribel

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**Sent:** 5/26/2020 7:59:43 AM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**Subject:** FW: FDA Approval Letter  
**Attachments:** EUA-solgent-diaplex-letter\_0.pdf

Hi Jennifer,

The Governor of the Northern Mariana Islands received the attached letter from the South Korean company regarding their EUA approval for their test kit. The Governor would like to verify the letter. Any assistance you can offer would be greatly appreciated.

Erica

---

**From:** Jason Osborne <jason@turnberrysolutionsllc.com>  
**Sent:** Tuesday, May 26, 2020 7:38 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>  
**Subject:** FDA Approval Letter

Erica,

Governor Torres received the attached unsigned letter from the South Korean company regarding their EUA approval for their test kit.

The Governor has asked me to verify that it is in fact approved before he purchases any of their kits.

Would you be able to verify it for us?

Thanks Jason Osborne  
CNMI Washington Office Director

Jason Osborne  
202-744-0639

---

**Sent:** 5/26/2020 9:37:45 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: FDA Approval Letter  
**Attachments:** EUA-solgent-diaplex-letter\_0.pdf

God m

---

**From:** Jason Osborne <jason@turnberrysolutionsllc.com>  
**Sent:** Tuesday, May 26, 2020 7:38 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>  
**Subject:** FDA Approval Letter

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The Governor has asked me to verify that it is in fact approved before he purchases any of their kits.

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Thanks Jason Osborne  
CNMI Washington Office Director

Jason Osborne  
202-744-0639

---

**Sent:** 5/27/2020 8:06:47 AM  
**To:** OC OCC Biologics Team Assignments [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1802635c07ae46ca83b2021f0d85cc88-OCOCCBiolog]  
**Subject:** Follow Up Questions from NCSL Vaccine Webinar  
**Attachments:** 5 26 2020 NCSL COVID 19 Webinar Follow Up Questions OP.docx

Good morning OCC,

Attached are follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL) a few weeks ago. Both CBER and CDER have provided responses. These questions and answers will be shared publicly on NCSL's webpage. Please review and clear at your earliest convenience.

Thank you for your assistance with this request.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**Sent:** 5/27/2020 11:30:05 AM  
**Subject:** FW: Request from WI Legislative Staff re: biologic vaccine licensure process.  
**Attachments:** (Clean) 20200522 Wisconsin Qs COVID 5-8-2020 vaccine.docx

Hi Prakash,

Karen suggested that I check with you, to see if the JIC needs to clear this document even though OCC already has reviewed it.

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, May 27, 2020 9:20 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Fwd: Request from WI Legislative Staff re: biologic vaccine licensure process.

Should send to Prakash in ol who handles cber and covid. Ask him if He thinks the JIC needs to clear even tho occ already has

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** May 26, 2020 at 11:47:00 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Sorry I didn't get back to you on this earlier today. I am not sure about further clearance from OPLIA. Let me check. In the meantime, maybe tell Haley we are only responding to the FDA-related questions so they can pursue responses from other agencies?

Talk tomorrow. Karen

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, May 22, 2020 3:20 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Request from WI Legislative Staff re: biologic vaccine licensure process.

Good afternoon Karen,

IGA received a request from the National Conference of State Legislatures (NCSL) on behalf of a state legislative staffer with questions about the biologic vaccine licensure process. The person is working on a publication on vaccine development. Attached are the FDA answers to the WI legislative staffer questions. FDA is only answering questions 2-4 and 7. CBER drafted the responses to 2-4 and the response to question 7 is from cleared reactive TPs. OP and OCC have already cleared the document. Checking to see whether this should go through OPLIA clearance before sending it back to NCSL.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Hurwitz, Zahava <Zahava.Hurwitz@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 5:33 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; OP Policy Review Team <OPPolicyReviewTeam@fda.hhs.gov>  
**Cc:** Flamm, Eric <Eric.Flamm@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Hi Erica. Sorry that this slipped by me when I was covering the Policy Inbox that week. Recognizing that events have changed, I made some suggested edits to reflect new information and new resources on our website. There are references to new cleared materials, but I defer to IGA if you think it would help to have OCC look again.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 4:33 PM  
**To:** OP Policy Review Team <OPPolicyReviewTeam@fda.hhs.gov>  
**Cc:** Flamm, Eric <Eric.Flamm@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff re: biologic vaccine licensure process.

Good afternoon OP,

Checking on the status of this request.

Thanks,

Erica

---

**From:** White, Erica  
**Sent:** Friday, May 8, 2020 11:00 AM  
**To:** OP Policy Review Team <OPPolicyReviewTeam@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Request from WI Legislative Staff re: biologic vaccine licensure process.

Good morning OP,

IGA received a request from the National Conference of State Legislatures (NCSL) on behalf of a state legislative staffer with questions about the biologic vaccine licensure process. The person is working on a publication on vaccine development. Attached are the FDA answers to the WI legislative staffer questions. FDA is only answering questions 2-4 and 7. CBER drafted the responses to 2-4 and the response to question 7 is from cleared reactive TPs. Please review and clear the attached document at your earliest convenience.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



---

**Sent:** 5/28/2020 8:29:17 AM  
**To:** Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**Subject:** Re: Coronavirus (COVID-19) Update: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection

Everything we send

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** May 27, 2020 at 10:51:41 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FW: Coronavirus (COVID-19) Update: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection

Will this be in Daily Update so no need to outreach separately?

**From:** U.S. Food and Drug Administration <fda@info.fda.gov>  
**Sent:** Wednesday, May 27, 2020 8:39 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection

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# Coronavirus (COVID-19) Update: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection

Today the U.S. Food and Drug Administration took a new step to support the agency's evaluation of diagnostic tests for COVID-19, by providing a SARS-CoV-2 reference panel. Reference panels are an additional step to ensure the quality of the tests, validation of new assays, test calibration, and monitoring of assay performance. Nucleic acid tests identify infection by confirming the presence of a virus' genetic material (RNA) and the FDA-supplied reference panel provides developers access to this material. The FDA's reference panel is an independent performance validation step for diagnostic tests of SARS-CoV-2 infection that are being used for clinical, not research, purposes. The FDA panel is available to ...

[Read More](#)

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U.S. Food and Drug Administration  
10903 New Hampshire Avenue, Silver Spring, MD 20993  
1-888-INFO-FDA (1-888-463-6332)  
[Privacy Policy](#) | [www.fda.gov](http://www.fda.gov)



---

**From:** Erica.White@fda.hhs.gov [Erica.White@fda.hhs.gov]  
**Sent:** 5/28/2020 9:04:29 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup May 28, 2020

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** FDA Office of Media Affairs <news@prnewswire.com>  
**Date:** May 28, 2020 at 7:56:35 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup



**FOR IMMEDIATE RELEASE**

**Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- The FDA issued an Emergency Use Authorization for the Stryker Sustainability Solutions (SSS) VHP N95 Respirator Decontamination System (RDS). This product uses vapor hydrogen peroxide (VHP) to decontaminate compatible N95 respirators that are, or potentially are, contaminated with SARS-CoV-2 or other pathogenic microorganisms for multiple-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of face-filtering respirators (FFRs) resulting from the Coronavirus Disease 2019 (COVID-19) pandemic. N95 respirators containing cellulose-based materials are incompatible with the SSS VHP N95 RDS. This system is operated by employees of Stryker Sustainability Solutions, whose facilities are designed to allow adequate space for receiving respirators for decontamination, visually inspecting respirators for gross contamination or damage, exposing respirators to VHP, and packaging or labeling them for return to the sender so as to minimize contamination and ensure orderly handling procedures. With respirators limited to a maximum of three decontaminations, each is permanently marked to indicate the number of decontamination cycles it has undergone.
- Yesterday, the FDA further supported its effort to evaluate diagnostic tests of COVID-19 by providing a SARS-CoV-2 reference panel. This panel is an independent performance validation step for diagnostic tests of SARS-CoV-2 infection that are being used for clinical, not research, purposes. The FDA panel is available to commercial and laboratory developers who are interacting with the FDA through the pre-emergency use

authorization (EUA) process or whose tests have been issued an EUA. The FDA will provide the reference panel to developers at the appropriate stage in the process. There is no need for these test developers to take additional action in order to receive the reference panel.

- Testing updates:

- During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted, or said they will be submitting, EUA requests to the FDA for tests that detect the virus or antibodies to the virus.

- To date, the FDA has authorized 113 tests under EUAs, which include 100 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

###

**Media Contact:** [Lee.Herring@fda.hhs.gov](mailto:Lee.Herring@fda.hhs.gov), 240-402-6386

**Consumer Inquiries:** 888-INFO-FDA

*The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 5/28/2020 9:45:32 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) ; emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup May 28, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- The FDA issued an Emergency Use Authorization for the Stryker Sustainability Solutions (SSS) VHP N95 Respirator Decontamination System (RDS). This product uses vapor hydrogen peroxide (VHP) to decontaminate compatible N95 respirators that are, or potentially are, contaminated with SARS-CoV-2 or other pathogenic microorganisms for multiple-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of face-filtering respirators (FFRs) resulting from the Coronavirus Disease 2019 (COVID-19) pandemic. N95 respirators containing cellulose-based materials are incompatible with the SSS VHP N95 RDS. This system is operated by employees of Stryker Sustainability Solutions, whose facilities are designed to allow adequate space for receiving respirators for decontamination, visually inspecting respirators for gross contamination or damage, exposing respirators to VHP, and packaging or labeling them for return to the sender so as to minimize contamination and ensure orderly handling procedures. With respirators limited to a maximum of three decontaminations, each is permanently marked to indicate the number of decontamination cycles it has undergone.

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- To date, the FDA has authorized 113 tests under EUAs, which include 100 molecular tests, 12 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

---

**Sent:** 5/29/2020 9:57:30 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Missouri Companies making PPE

Hi Karen,

How's this as a response?

Good afternoon Michelle,

Thank you for contacting the Food & Drug Administration Center about marketing your product in the United States to assist with PPE availability concerns due to coronavirus.

Last week, FDA issued guidance on Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by health care professionals in healthcare settings.

This morning, FDA issued guidance on Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency. FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of gowns, other apparel, and gloves and helping to expand the availability of surgical apparel for health care professionals, including gowns, hoods, togas, and surgeon's and patient examination gloves during this public health emergency.

If you have questions related to this, please let me know. My contact information is below. For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



---

**From:** Earley, Rosemary <[Rosemary.Earley@fda.hhs.gov](mailto:Rosemary.Earley@fda.hhs.gov)>  
**Sent:** Monday, March 30, 2020 10:52 AM

**To:** Hataway, Michelle <Michelle.Hataway@ded.mo.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Missouri Companies making PPE

Hi Michelle,

Thank you for contacting us and for working to get more companies online for PPE manufacture. I'm copying Erica White in Intergovernmental Affairs as she's in the best position to get you that information.

All best,  
Rosie



**Rosemary Earley, DVM** | *Congressional Affairs Specialist*

● Office of Congressional Appropriations

● Office: (301) 796-6186

Cell: (b)(6)

rosemary.earley@fda.hhs.gov

---

**From:** Hataway, Michelle <Michelle.Hataway@ded.mo.gov>  
**Sent:** Monday, March 30, 2020 10:13 AM  
**To:** Earley, Rosemary <Rosemary.Earley@fda.hhs.gov>  
**Subject:** Missouri Companies making PPE

Rosemary,

Senator Blunt's office shared your contact information with me. I work for the Missouri Department of Economic Development. We are working with a few Missouri companies on starting to manufacture PPE. I was hoping you could give me some guidance on the 510(k) premarket notification that is required for some of the PPE. I've been to the website and found the FAQs.

I'm looking for information on how we can help companies that are interested in making PPE navigate this process.

If you aren't the correct contact—can you please refer me to the appropriate person?

Thank you,

Michelle Hataway  
MO Dept of Economic Development  
573.751.9051 Work  
(b)(6) Mobile  
Michelle.Hataway@ded.mo.gov  
301 W. High St. Suite 720  
Jefferson City, MO 65101

---

**Sent:** 6/1/2020 1:48:12 PM  
**To:** Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]  
**Subject:** Question from NCSL

Hi Darcie,

Below is a follow-up question from Dr. Shah's participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL) a few weeks ago. This question is one of several that FDA received and have addressed; however, we believe the answer to this question would be better addressed by HHS. Any assistance you can provide in answering this question would be greatly appreciated.

- **Even if an effective and safe vaccine is developed, how long would it take to produce and distribute it to large parts of the U.S. population?**

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov





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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 6/1/2020 3:19:19 PM  
**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Gomez, Rachel A. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb9b744b3c3b4e3ea335c72bc527b8d8-Rachel.Gomez]; White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: OL Reactive TPs for COVID Briefings  
**Attachments:** Reactive TPs 5.28.20.docx

fyi

---

**From:** Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>  
**Sent:** Friday, May 29, 2020 8:52 AM  
**To:** Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Peddicord, Sarah <Sarah.Peddicord@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>  
**Cc:** Adleberg, Jill <Jill.Adleberg@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Burns, Corey <Corey.Burns@fda.hhs.gov>; Colonius, Tristan <Tristan.Colonius@fda.hhs.gov>; Feingold, Daniel <Daniel.Feingold@fda.hhs.gov>; George, Bryan <Bryan.George@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Lexer, Susan <Susan.LexerSmith@fda.hhs.gov>; Lockheed, Matthew <Matthew.Lockheed@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Rosebraugh, Sydney <Sydney.Rosebraugh@fda.hhs.gov>  
**Subject:** OL Reactive TPs for COVID Briefings

Attached are OL's Reactive Talking Points, updated through yesterday.

Thank you.

**Andrew Tantillo, J.D.**

*Deputy Director*

Office of Legislation  
U.S. Food and Drug Administration  
301-796-8919 M: 202-809-2989  
andrew.tantillo@fda.hhs.gov



---

**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 6/2/2020 9:17:15 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@mshd.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 2, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- The agency issued a new [FDA Voices](#), titled [Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety](#), and bylined by Stephen M. Hahn, M.D., Commissioner of Food and Drugs, and Frank Yiannas, Deputy Commissioner for Food Policy and Response. In March, the FDA was a few days away from announcing the release of the New Era of Smarter Food Safety Blueprint when the FDA's focus turned to the COVID-19 pandemic. Plans for the New Era initiative were rightfully put on hold in order to prioritize the agency's COVID-19 response. The FDA will release the blueprint in the coming weeks, outlining plans over the next decade to create a more digital, traceable, and safer food system.

- The FDA published guidance, titled [Institutional Review Board \(IRB\) Review of Individual Patient Expanded Access Requests for Investigational Drugs and Biological Products During the COVID-19 Public Health Emergency](#) [Guidance for IRBs and Clinical Investigators](#), which includes recommendations regarding procedures for single IRB member review. This is in response to physician requests for a waiver from the requirement for full IRB review. The guidance recommendations also address factors to consider when assessing potential benefits and risks for a particular patient being treated under expanded access.

- The FDA added a second ventilator developed by NASA to the list of authorized ventilators, ventilator tubing connectors and ventilator accessories under the ventilator emergency use authorization (EUA) that was issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in health care settings to treat patients during the COVID-19 pandemic. The NASA VITAL (Ventilator Intervention Technology Accessible Locally) is intended to last three to four months and is specifically tailored to provide respiratory support for COVID-19 patients who are experiencing respiratory failure or insufficiency. Where the first NASA ventilator relied on wall gas as the pressure source, the second ventilator uses an internal compressor for its energy source. The device is designed to be built with components outside the current medical device supply chain and therefore does not impact the existing supply chain of currently made ventilators.

- The FDA added an emergency resuscitator for the Fitbit Flow to the list of authorized ventilators, ventilator tubing connectors and ventilator accessories under the ventilator emergency use authorization (EUA). The Fitbit Flow is a continuous respiratory support system that includes an FDA-cleared Manual Resuscitator. The accessory is an AMBU bag with audible and visual alarms that aid the performance of the manual resuscitator for continuous breathing. This design is intended for use in treating patients with COVID-19.

- The FDA, in collaboration with the European Medicines Agency (EMA), provided procedural assistance to sponsors and applicants who anticipate submission of pediatric product development plans for the treatment and prevention of COVID-19. In issuing this [Common Commentary](#), the FDA and EMA aspire to streamline administrative processes and facilitate efficient submission of an initial Pediatric Study Plan (iPSP) and Paediatric Investigation Plan (PIP).

- The FDA recognizes the vital role of health professionals in the fight against COVID-19. In order to help health professionals quickly and easily access FDA resources, we created a new [web page](#), titled [Coronavirus Disease 2019 \(COVID-19\) Resources for Health Professionals](#). This page contains links to FDA emergency use authorizations; information about personal protective equipment and other medical products for use during COVID-19.

- Testing updates:

- During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted, or said they will be submitting, EUA requests to the FDA for tests that detect the virus or antibodies to the virus.

- To date, the FDA has authorized 119 tests under EUAs, which include 103 molecular tests, 15 antibody tests, and 1 antigen test.

#### **Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**Sent:** 6/3/2020 8:47:47 AM  
**To:** IGA [IGA@fda.hhs.gov]  
**Subject:** Fwd: Coronavirus (COVID-19) Update: Daily Roundup June 2, 2020

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

---

**From:** FDA Office of Media Affairs <news@prnewswire.com>  
**Date:** at 7:32:35 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup



**FOR IMMEDIATE RELEASE**  
**June 2, 2020**

### **Coronavirus (COVID-19) Update: Daily Roundup**

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- The agency issued a new FDA Voices, titled Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety, and bylined by Stephen M. Hahn, M.D., Commissioner of Food and Drugs, and Frank Yiannas, Deputy Commissioner for Food Policy and Response. In March, the FDA was a few days away from announcing the release of the New Era of Smarter Food Safety Blueprint when the FDA's focus turned to the COVID-19 pandemic. Plans for the New Era initiative were rightfully put on hold in order to prioritize the agency's COVID-19 response. The FDA will release the blueprint in the coming weeks, outlining plans over the next decade to create a more digital, traceable, and safer food system.
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  - During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted, or said they will be submitting, EUA requests to the FDA for tests that detect the virus or antibodies to the virus.
  - To date, the FDA has authorized 119 tests under EUAs, which include 103 molecular tests, 15 antibody tests, and 1 antigen test.

**Additional Resources:**

- FAQs on Testing for SARS-CoV-2
- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)
- Coronavirus Disease 2019 (COVID-19)

###

**Media Contact:** Lee.Herring@fda.hhs.gov, 240-402-6386

**Consumer Inquiries:** 888-INFO-FDA

*The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.*

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**From:** Meister, Karen G [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7F2CDCD99E784C6CB3E8BF491FEE037F-KMEISTER]  
**Sent:** 6/8/2020 11:25:25 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** FW: FDA MedWatch - Transport Media Safety Risk: Letter to Clinical Laboratory Staff and Health Care Providers

Should this go to state health depts?

**From:** U.S. Food and Drug Administration <fda@info.fda.gov>  
**Sent:** Friday, June 05, 2020 5:54 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FDA MedWatch - Transport Media Safety Risk: Letter to Clinical Laboratory Staff and Health Care Providers

If your email program has trouble displaying this email, view it as a [web page](#).

## *MedWatch - The FDA Safety Information and Adverse Event Reporting Program*

A *MedWatch* Safety Alert was added to the *FDA Medical Device Safety* web page.

**TOPIC:** Transport Media Safety Risk: Letter to Clinical Laboratory Staff and Health Care Providers - Use of Compatible Transport Media with SARS-CoV2 Tests that Use Bleach

**AUDIENCE:** Health Professional, Laboratory, Risk Manager

**ISSUE:** The FDA is reminding laboratory staff to use transport media (the liquid that maintains the viability of a specimen sample while it's transported to a laboratory) that are compatible with the SARS-CoV-2 testing platforms and laboratory processes to analyze samples collected from people who are being tested for SARS-CoV-2. There is a risk of exposure to harmful cyanide gas, a by-product of a reaction between guanidine thiocyanate or similar chemicals and bleach (sodium hypochlorite), when certain transport media are used with an incompatible testing platform or laboratory process.

There have been no injuries reported to the FDA associated with exposure to cyanide gas as a result of using incompatible media with testing platforms.

**BACKGROUND:** PrimeStore MTM (LH-1-02\* and LH-1-03\*), Zymo DNA/RNA Shield, and Spectrum Solutions Saliva Collection Device contain a transport medium which maintains patient specimens while they are transported to a laboratory for RNA and DNA testing.

These media contain guanidine thiocyanate or similar chemicals, which produces a hazardous chemical reaction that releases cyanide gas when exposed to bleach (sodium hypochlorite). Bleach should not be used in a testing platform, or in laboratory processes. Many laboratories may use bleach in their cleaning or decontamination processes in response to laboratory spills.

**RECOMMENDATION:** The FDA recommends that clinical laboratory staff and health care providers:

- Do not use PrimeStore MTM, Zymo DNA/RNA Shield, Spectrum Solutions Saliva Collection Device, or any other transport media containing guanidine thiocyanate or similar chemicals with the Hologic Panther or Panther Fusion Systems due to a disinfecting step involving bleach that is specific to the testing platform.
- Review the manufacturer's instructions for the testing platform used in your laboratory about which transport media should be used.
- Do not use cleaning agents containing bleach on testing platforms that use guanidine thiocyanate or similar chemicals, either in transport media or sample processing reagents.
- Do not separate transport media tubes from the manufacturer's labeling.
- If you can identify the contents of the tube through associated packaging or information from the distributor, you may place a label on a specimen collection tube that does not have a label identifying the type of transport media inside. If you do not have a label, you may contact the manufacturer to obtain one.
- If you cannot identify the type of transport media in the specimen collection tubes or if you do not know if the transport media contains guanidine thiocyanate or similar chemicals as an ingredient, handle tubes as if they contain guanidine thiocyanate or similar chemicals.

Health professionals are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online.
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the form, or submit by fax to 1-800-FDA-0178.

[Read Letter to Health Care Providers](#)

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U.S. Food and Drug Administration  
10903 New Hampshire Avenue, Silver Spring, MD 20993  
1-888-INFO-FDA (1-888-463-6332)  
Privacy Policy | [www.fda.gov](http://www.fda.gov)





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**Sent:** 6/8/2020 1:35:55 PM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Ross, Aftin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=340198e1a213488b81fa54f942ae430e-Aftin.Ross]; Schwartz, Suzanne [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Ricci, Linda J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2e0eac1867d40a3b39c4031cb35490f-LJS]  
**Subject:** FW: Please review response to State Rep. Allen re: Sterigenics.  
**Attachments:** EtO Erick Allen Response.CDRH Cleared - 4-8-2020 - OCC.docx

Hi Jennifer,

Please address the comments OCC placed in the draft response to Rep Allen. Once those are resolved I will send to OPLIA for clearance.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Sent:** Wednesday, April 8, 2020 1:03 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>  
**Subject:** RE: Please review response to State Rep. Allen re: Sterigenics.

Hi Karen and Erica,

Thank you for your patience while we conferred with (b)(5) OCC clears the draft response to State Rep. Allen with changes in the attached. Happy to chat if you have any questions.

Thank you,  
Jaycie

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Wednesday, April 8, 2020 12:30 AM

**To:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Please review response to State Rep. Allen re: Sterigenics.

Of course. Thanks for the update Jaycie. Please keep Erica on the chain because I am off the rest of the week and am not sure I'll be checking email. Thanks for keeping it moving though...

Karen

---

**From:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Sent:** Tuesday, April 07, 2020 7:04 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Please review response to State Rep. Allen re: Sterigenics.

Karen,

(b)(5) I needed to send my proposed revisions to the letter to my manager for review. I am not certain whether he will get around to reviewing tonight. I'll be in touch as soon as I hear back.

Thank you for your patience and have a good night!

Best,  
Jaycie

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 7, 2020 7:55 AM  
**To:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 (b)(6) White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Please review response to State Rep. Allen re: Sterigenics.

That would be fabulous. I am so sorry it sat in my inbox for a day but I was triaging so many things I didn't get to my inbox until 3 AM!!!!

---

**From:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Sent:** Tuesday, April 07, 2020 7:53 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 (b)(6) White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Please review response to State Rep. Allen re: Sterigenics.

Hi Karen,

I can likely get to this by COB today. Will that timing work for you?

Thank you,  
Jaycie

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, April 7, 2020 3:19 AM  
**To:** Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>

**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Please review response to State Rep. Allen re: Sterigenics.

Thanks Jaycie- Please let us know when you can review. We know you are busy! Thanks. Karen

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Sunday, April 05, 2020 1:57 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** RE: PLEASE GET CDRH CLEARED

Karen,

Attached are CDRH's cleared responses to GA State Rep. Allen. Please let us know if you have any questions.

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 - Celi (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:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 8:00 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Subject:** RE: PLEASE GET CDRH CLEARED

Thanks all.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Thursday, March 26, 2020 7:41 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne

<Suzanne.Schwartz@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** RE: PLEASE GET CDRH CLEARED

No worries – I just pinged folks so we hope to have this soon.

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:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Sent:** Thursday, March 26, 2020 4:59 PM

**To:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** RE: PLEASE GET CDRH CLEARED

Sorry to nudge. Just checking on status.

---

**From:** Meister, Karen G

**Sent:** Wednesday, March 25, 2020 6:21 PM

**To:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** PLEASE GET CDRH CLEARED

This is it. Thanks!

---

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

**Sent:** Wednesday, March 25, 2020 6:10 PM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** RE: SO IS RESPONSE CDRH CLEARED?

Hi Karen,

No this is not yet CDRH cleared. Can someone put this into a word document and send around to Jeff, Ellen, and Suzanne for review?

Linda Ricci, MME MPH  
*Director*

Division of All Hazard Response, Science and Strategic Partnerships (DARSS)  
Office of Strategic Partnerships and Technology Innovation (OST)  
CDRH | Food and Drug Administration  
Tel: 301-796-6325

Cell: (b)(6)  
Linda.Ricci@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=7010&S=E>

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Sent:** Wednesday, March 25, 2020 5:23 PM

**To:** Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** SO IS RESPONSE CDRH CLEARED?

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

**Sent:** Wednesday, March 25, 2020 5:11 PM

**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** RE: HEADS UP: Response to Letter from State Rep. Allen re: FDA letter to Gov. Kemp - Sterigenics and EtO

I totally skirted the issue

Linda Ricci, MME MPH  
*Director*

Division of All Hazard Response, Science and Strategic Partnerships (DARSS)  
Office of Strategic Partnerships and Technology Innovation (OST)  
CDRH | Food and Drug Administration  
Tel: 301-796-6325

Cell: (b)(6)  
Linda.Ricci@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=7010&S=E>

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Sent:** Wednesday, March 25, 2020 5:01 PM

**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>  
**Subject:** RE: HEADS UP: Response to Letter from State Rep. Allen re: FDA letter to Gov. Kemp - Sterigenics and EtO

Re-reading the draft, question 5 is really asking how we found out about the Sterigenics problem. Was it from Sterigenics or a supplier? (b)(5)

1) **Has the FDA been in contact with manufacturers who have a pipeline issue or was the request made from Sterigenics directly to the FDA?**

(b)(5)

**From:** Meister, Karen G  
**Sent:** Wednesday, March 25, 2020 4:03 PM  
**To:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>  
**Subject:** RE: HEADS UP: Response to Letter from State Rep. Allen re: FDA letter to Gov. Kemp - Sterigenics and EtO

I know. If anyone needs the Sterigenics letter, I'm attaching that too.

**From:** Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 5:46 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>  
**Subject:** Re: HEADS UP: Response to Letter from State Rep. Allen re: FDA letter to Gov. Kemp - Sterigenics and EtO

Karen,

I note the letter regarding BD is attached, not the one to (b)(5)

CDRH will look at the SP link,  
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  
Mobil: (b)(6)

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** March 25, 2020 at 2:07:55 AM EDT  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>, White, Erica <Erica.White@fda.hhs.gov>, Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>  
**Subject:** HEADS UP: Response to Letter from State Rep. Allen re: FDA letter to Gov. Kemp - Sterigenics and EtO

Hi Jennifer-

This is my first letter referral to you as the JIC CDRH legislative lead, and I welcome your advice regarding process.

State Representative sent a letter to us in response to Dr. Hahn's letter to Gov. Kemp regarding PPE and Sterigenics asking 5 questions. Below is a sharepoint link of a draft response for your review and input. The incoming letter is embedded in the draft response. We only had information related to questions one and two. We need CDRH to provide responses to 3,4,5 and of course review, comment, edit questions 1 and 2 (no pride of authorship). We are attaching the letter sent to GA EPD re: BD because we reference it in the draft response and thought it would be helpful to have.

Please let us know about clearances. We are happy to provide Agency clearances but we want to comply with JIC process as well. I am copying Suzanne, Linda and Aftin with whom we worked on this issue already. We will get back to you about a deadline. Need to ask Erika.

<http://sharepoint.fda.gov/orgs/OC-OL/Cross%20Cutting/EtO%20Erick%20Allen%20Response.docx>

Thank you!

Karen

*Karen Meister, J.D.  
Acting Director, Intergovernmental Affairs  
Senior Advisor, Office of Legislation  
Office of the Commissioner/OPPLIA  
U.S. Food and Drug Administration  
(301) 796-8916 office*

**(b)(6)** *(work cell)  
(personal cell- I will call you back on work phone)*

---

**Sent:** 6/9/2020 8:26:21 AM  
**To:** Temple, Amy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=075cf6e3522d41118c57c29df52ba21b-Amy.Wright]  
**CC:** Richards, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04b2b41d286c4c12b60b827b5fb0c96c-richards]; Raine, Kristine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=382810b11ef947adae21d0f7876d8ede-RaineK]; Bell, Maureen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef58fe180a4f466e809ea1eaabec2f41-BellM]  
**Subject:** RE: Follow Up Questions from Vaccine Webinar  
**Attachments:** 5 28 2020 NCSL COVID 19 Webinar Follow Up Questions.docx

Good morning,

The questions are currently with OPLIA for clearance.

---

**From:** Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Sent:** Friday, June 5, 2020 12:42 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Richards, Paul <Paul.Richards@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Good afternoon Erica,

Have the Q and A's been cleared by OCC and OP? If so, can you forward the cleared response? If the response has been cleared, did you send the response to NCSL?

Best,

Amy

**Amy Temple**  
*Health Communications Specialist*

Center for Biologics Evaluation and Research  
Office of Communications, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 800-835-4709  
OCOD@fda.hhs.gov



*This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.*

---

**From:** Temple, Amy  
**Sent:** Wednesday, May 20, 2020 4:33 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>



**Cc:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>

**Subject:** RE: Follow Up Questions from Vaccine Webinar

You're welcome!

Amy Temple

Supervisory Health Communications Specialist (Acting)

Center for Biologics Evaluation and Research  
Office of Communications, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 800-835-4709  
OCOD@fda.hhs.gov



*This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.*

---

**From:** White, Erica <Erica.White@fda.hhs.gov>

**Sent:** Wednesday, May 20, 2020 4:31 PM

**To:** Temple, Amy <Amy.Temple@fda.hhs.gov>

**Cc:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>

**Subject:** RE: Follow Up Questions from Vaccine Webinar

Thanks. I appreciate that information. The questions and answers are going to OCC and OP also for clearance.

Erica

---

**From:** Temple, Amy <Amy.Temple@fda.hhs.gov>

**Sent:** Wednesday, May 20, 2020 4:30 PM

**To:** White, Erica <Erica.White@fda.hhs.gov>

**Cc:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>

**Subject:** RE: Follow Up Questions from Vaccine Webinar

Hi Erica,

We thought you should be aware that according to the NCSL webinar, they plan to post FDA's answers to the follow-up questions on their website.

I apologize for forgetting to mention that in my previous email.

Amy

Amy Temple  
Supervisory Health Communications Specialist (Acting)

Center for Biologics Evaluation and Research  
Office of Communications, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 800-835-4709  
OCOD@fda.hhs.gov



*This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.*

---

**From:** Temple, Amy  
**Sent:** Wednesday, May 20, 2020 4:17 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>  
**Subject:** RE: Follow Up Questions from Vaccine Webinar

Good afternoon Erica,

Attached please find CBER's responses to the follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL).

Please note in the comments that we recommend reaching out to CDER for the response to the question "What is the timeline for therapies?" And to the Office of Minority Health for the question "What kind of outreach is used in the Latino Hispanic communities?"

Please feel free to contact me if you have any questions.

Best regards,

Amy

Amy Temple  
Supervisory Health Communications Specialist (Acting)

Center for Biologics Evaluation and Research  
Office of Communications, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 800-835-4709  
OCOD@fda.hhs.gov



*This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.*

---

**From:** Raine, Kristine <Kristine.Raine@fda.hhs.gov>  
**Sent:** Friday, May 1, 2020 9:24 AM  
**To:** Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Cc:** Bell, Maureen <Maureen.Bell@fda.hhs.gov>  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Hi Amy,

Good Morning. We received another email from IGA asking CBER to assist in providing answers to the below follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures a few weeks ago. Please have CBER keep us in the loop on any responses, and as always if you need CBER Exec Sec's help, please let us know.

Thanks,

Kristine

***Kristine L. Raine, M.S.***  
*Consumer Safety Officer  
CBER Consumer Affairs Branch  
Phone: 240-402-8145  
Fax: 301-595-1243  
Email: Kristine.Raine@fda.hhs.gov*

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, May 01, 2020 9:09 AM  
**To:** CBER Exec. Sec. <cber\_execsec@fda.hhs.gov>  
**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Good morning CBER Exec Sec,

Below are follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL) a few weeks ago. Any assistance you can provide with answering the questions below is greatly appreciated. The suggested Center for a response is in parenthesis next to each question.

Thank you for your assistance with this request.

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>  
**Sent:** Thursday, April 30, 2020 4:18 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Follow Up Questions from Vaccine Webinar

Good Afternoon Chris and Erica,

I first want to say a huge thanks for all you and your team has helped us with during this time. Below are the questions that came in for Dr. Shah during the webinar but we obviously didn't have time to get to all of them. Would you all be able to take a look and provide any answers that you can? Understandably you may not be able to answer all of them or if some are more directing our members to a resource to read up on we would welcome that. Let me know if you have any questions and thank you again for all you have done for our members and staff!

- It was reported that Oxford University is testing a vaccine that could be available by August of 2020, This would be an incredibly rapid turnaround for a vaccine. Do you feel this might in fact happen? (CBER)
- Even if an effective and safe vaccine is developed, how long would it take to produce and distribute it to large parts of the U.S. population? (CBER)
- What is the actual number of weeks or months on the fast track program? (CBER)
- What is the timeline for therapies? (CBER)
- What kind of outreach is used in the Latino Hispanic communities? (Not sure what they are asking, or whom this would go to?)
- Have there been challenges with participation of Hispanics and African Americans in the clinical trials, as often is the case with the development of other vaccines/medications? (CBER)
- Have there been any supply challenges on the use of existing medicines to treat and/or alleviate symptoms of Covid 19? Can you provide us an brief example of such? (CDER)
- After talking to some physicians on the ER front lines I have the following question: Is there any protocol (or upcoming protocol) for prophylactic use of medications for healthcare professionals dealing with COVID-19 patients? There is apparently a great deal of confusion among them about this. (CDER)

Thank You,

Haley Nicholson  
National Conference of State Legislatures  
Senior Policy Director, Health & Human Services  
State-Federal Affairs  
202-624-8662 (o)



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**From:** Gomez, Rachel A. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB9B744B3C3B4E3EA335C72BC527B8D8-RACHEL.GOME]  
**Sent:** 6/9/2020 8:26:44 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** Just sharing the latest Covid info in Pipelines

Just sharing the latest, in case you don't have

# COVID-19 VITALS

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MONDAY, JUNE 08, 2020

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## Priorities Driving the Day

### Targeted for release tomorrow, 09 June

- **Press statements:**
- FDA Authorizes First Next Generation Sequence Test for Diagnosing COVID-19
- **Web updates:**
- CDER WL: Organic Beauty Products
- **Stakeholders:**
- CDRH: Webinar Series - Respirators for Health Care Personnel Use during COVID-19 Pandemic
- CDER: Division of Drug Information CURE ID webinar for HCPs - Capturing Clinician's Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-19 – Speaker Heather Stone (OMP)
- CFSAN: Support CDC guidance on farm workers and employers+ stakeholder call
- Pharmaceutical Care Management Association (PCMA) webinar (Drs. Shah and Guram)

### Look ahead for the week of 08 June

- **Press statements:**
- FDA provides update on continuity of user fee related work for medical product reviews during pandemic
- FDA Provides Update on Foreign, Domestic Routine Inspections Across Products, Announces New Approach to State Produce Inspections potentially
- **CDRH:**
- Upcoming IIE guidances:
  - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications

(b)(5)

- **CDER:**
- Warning letter: Organic-beauty-recipes.com selling essential oils
- Updated Remdesivir HealthCare Professional Fact Sheets
- Revised EUA fact sheets for remdesivir, to update info on dosing and clinical trials, and add info on HCQ/CQ drug interaction with remdesivir
- **CFSAN:**

- Checklist (w/CVM): Employee Health and Food Safety Checklist for Human and Animal Food Operations During COVID-19

- **ORA:** [redacted] **(b)(5)**

## Pipelines & Supply Chain

- **Diagnostics:**

- **DX EUAs Issued: 128 [+3] (72 [+1] Molecular, 35 [+0] Molecular Blanket LDT EUA, 19 [+2] Serological, 1 [+0] antigen, 1 [+0] home collection kit)**

- **DX EUAs declined issuance: 3 [+1] (0 [+0] molecular; 3 [+1] serological; 0 [+0] antigen)**

- **PPE:**

- CDRH reissued authorizations for five N95 decontamination system EUAs to remove Non-NIOSH-Approved respirators made in China (KN95s) and exhalation valves from the scope of the authorizations

- CDRH reissued authorizations for two N95 decontamination system EUAs to remove exhalation valves from the scope of the authorizations (note: these authorizations never included KN95 decontamination)

- CDRH revised and reissued the authorization of an umbrella EUA for Imported, Non-NIOSH-Approved Disposable FFRs

- CDRH revised and reissued the authorization of an umbrella EUA for Imported, Non-NIOSH-Approved Disposable FFRs Manufactured in China

- [redacted] **(b)(5)**

- **Ventilators:**

- CDRH has authorized **100 [+0]** ventilator products, **11 [+0]** ventilator tubing connector products, and **4 [+0]** ventilator accessory products to Appendix B of ventilator EUA

- **Biologics:**

- **Pre-INDs/INDs: 45+ pre-INDs, and 125+ INDs**

- **eINDs: 2,400+ eINDs granted for convalescent plasma**

- **COVID-19 Convalescent Plasma Expanded Access Program: 2,471 [+4] Sites, 8,018 [+131] Physicians, 28,246 [+1136] Patients, and 20,687 [+594] Infused**

- **Human Drugs:**

- **Pre-INDs/INDs: 435 [+1]** Pre-INDs have been submitted; **224 [+6]** INDs have been submitted; **139 [+3]** of which were issued 'Safe To Proceed' letters.

- **EUAs: 31 [+0]** EUAs have been submitted to CDER; **22 [+0]** CDER denied to issue; **3 [+0]** have been authorized; **6 [+0]** are under review.

- **eINDs: 1,305 [+0]** eINDs have been authorized to date.

- **Supply Chain:**

- **Guidance**

- **Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency** - permits alternate ways to verify the delivery and receipt of prescription drug samples and allows for the delivery of drug samples to patients' homes if requested by the licensed practitioner.

Rachel Gomez 郭瑞秋

Intergovernmental Affairs (IGA) - Detailee

Cell [redacted] **(b)(6)**

Assistant Country Director | U.S. Embassy, P.R. of China  
Office of Global Policy and Strategy - Office of Global Operations  
U.S. Food and Drug Administration

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**Sent:** 6/9/2020 1:22:17 PM  
**Subject:** FW: Question from NCSL

**(b)(5)**

**(b)(5)**

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**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 9, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact IGA@fda.hhs.gov for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- On June 8, 2020, the FDA approved an abbreviated new drug application for succinylcholine chloride injection USP 200 mg/10 mL, which is indicated in addition to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Side effects of succinylcholine chloride injection include anaphylaxis, hyperkalemia, and malignant hyperthermia.

The FDA recognizes the increased demand for certain products during the COVID-19 public health emergency, and we remain deeply committed to facilitating access to safe and effective medical products to help address critical needs of the American public.

- The FDA issued a warning letter to one company for selling a fraudulent COVID-19 product, as part of the agency's effort to protect consumers. The seller that received FDA's warning, [organic-beauty-recipes.com](https://www.organic-beauty-recipes.com), participates in the Amazon Associates program. As an Amazon associate, the company earns commissions on its website for promoting the sale on Amazon of certain products. One essential-oil product promoted by the site is accompanied by misleading claims that this product can mitigate, prevent, treat, diagnose, or cure COVID-19 in people. FDA requested the company immediately stop promoting and participating in the sale of the fraudulent COVID-19 product. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.

- Testing updates:

- To date, the FDA has authorized 128 tests under EUAs, which include 108 molecular tests, 19 antibody tests, and 1 antigen test.

#### **Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
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**Subject:** FOR REVIEW: June 23 E&C COVID Hearing -- HHS Draft Testimony for your review by 1 pm tomorrow, 6/12

**Attachments:** Draft HHS Testimony on COVID - E&C June 23 (2).docx

Good evening all,

Please see the attached draft testimony from HHS and clear by June 12, 1 pm. This is just a courtesy review so we are just looking for anything in the other OpDivs' portions of the testimony that would raise a flag for FDA.

Thanks!

Caitlin

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
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**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiox@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lilljan.shirlev@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 11, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- FDA issued an FDA Voices, titled [Rare Disease Therapy Development and Access Remain Top FDA Priorities During COVID-19](#), which explains that the FDA's work to advance treatments for rare diseases and help ensure continuity of care for patients with those diseases continues to be a top priority during the COVID-19 public health emergency.
- As part of the FDA's mission to protect consumers, the agency issued a warning letter to one company for selling fraudulent COVID-19-related products. The FDA letter warned the seller, [www.outoftheboxremedies.com](http://www.outoftheboxremedies.com), which offers iodine products for sale in the United States, citing misleading claims that the products can mitigate, prevent, treat, diagnose, or cure COVID-19 in people. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
- On June 10, 2020, the FDA [posted FAQs](#) to address questions related to the design, evaluation, labeling, and marketing of hospital beds, stretchers, and mattresses during the COVID-19 public health emergency.
- Testing updates:
  - To date, the FDA has authorized 135 tests under EUAs, which include 114 molecular tests, 20 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)



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**Sent:** 6/16/2020 2:48:12 AM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@gmail.com; emais.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**Subject:** Coronavirus (COVID-19) Update: FDA Encourages Recovered Patients to Donate Plasma for Development of Blood-Related Therapies

Good morning,

The FDA Intergovernmental Affairs team would like to bring to your attention that today FDA issued the following press release titled FDA Encourages Recovered Patients to Donate Plasma for Development of Blood-Related Therapies.

The entire announcement can be found at this link and below. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-encourages-recovered-patients-donate-plasma-development-blood>

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



### **Coronavirus (COVID-19) Update: FDA Encourages Recovered Patients to Donate Plasma for Development of Blood-Related Therapies**

*The following is attributed to FDA Commissioner Stephen M. Hahn, M.D.*

As part of the all-of-America approach to fighting the COVID-19 pandemic, the U.S. Food and Drug Administration has been working with partners across the U.S. government, academia and industry to expedite the development and availability of critical medical products to treat this novel virus. Today, we are providing an update on one potential treatment called convalescent plasma and encouraging those who have recovered from COVID-19 to donate plasma to help others fight this disease.

Convalescent plasma is an antibody-rich product made from blood donated by people who have recovered from the disease caused by the virus. Prior experience with respiratory viruses and limited data that have emerged from China suggest that convalescent plasma has the potential to lessen the severity or shorten the length of illness caused by COVID-19. It is important that we evaluate this potential therapy in the context of clinical trials, through expanded access, as well as facilitate emergency access for individual patients, as appropriate.

The response to the agency's recently announced national efforts to facilitate the development of and access to convalescent plasma has been tremendous. More than 1,040 sites and 950 physician investigators nationwide have signed on to participate in the Mayo Clinic-led expanded access protocol. A number of clinical trials are also taking place to evaluate the safety and efficacy of convalescent plasma and the FDA has granted numerous single patient emergency investigational new drug (eIND) applications as well.

As this work moves forward, the key to ensuring the availability of convalescent plasma to those in greatest need is getting recovered COVID-19 patients to donate plasma. The FDA has launched a new webpage to guide recovered COVID-19 patients to local blood or plasma collection centers to discuss their eligibility and potentially schedule an appointment to donate. The webpage also provides information for those interested in participating in the expanded access protocol, conducting clinical trials or submitting eIND applications. The American Red Cross has also set up a website for interested donors ([www.redcross.org/plasma4covid](http://www.redcross.org/plasma4covid)) and the FDA continues to work with others in this area to help encourage additional donations.

During this challenging time, many people are asking what they can do to contribute to the COVID-19 response. Those individuals who have recovered from COVID-19 could have an immediate impact in helping others who are severely ill. In fact, one donation has the potential to help up to four patients. Convalescent plasma can also be used to manufacture a biological product called hyperimmune globulin, which can similarly be used to treat patients with COVID-19.

People who have fully recovered from COVID-19 for at least two weeks can contact their local blood or plasma collection center today to schedule an appointment. We encourage individuals to consider donating and hope this information will serve as a helpful resource to facilitate this important act of kindness.

Additional Resources:

- [Coronavirus Disease \(COVID-19\)](#)
- [Donate COVID-19 Plasma](#)
- [American Red Cross: Plasma Donations from Recovered COVID-19 Patients](#)
- [Recommendations for Investigational COVID-19 Convalescent Plasma](#)
- [National Expanded Access Treatment Protocol](#)

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**Sent:** 6/16/2020 2:45:29 PM  
**To:** Tomasello, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5aa45d669024d87a822c2a7b33f652b-Jennifer.To]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Governor of Oregon - Department R/C

Hi Jennifer,

HHS has approved FDA moving forward with a call to Governor Brown. Before I reach out to the Gov's office, I want to make sure we have everything in place, b/c the turnaround time for the call may be short.

Do you have an idea who from CDRH would participate in the call, and their availability? I would hate to schedule something and a key team member be out.

---

**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Thursday, June 4, 2020 2:00 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Oh this is good news, thank you!

The questions are pretty straightforward. They are in desperate need for PPE and are urging us to do more, basically. We have a good story to tell on that.

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>

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Thursday, June 4, 2020 1:58 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>

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

**Subject:** FW: Governor of Oregon - Department R/C

This is good news. Please call Oregon and see if it's acceptable to them. If yes, find out who will be on the call because that will determine who we have on the call....whether just Jennifer is enough or whether she will need to bring in SMEs. (b)(5)

Thanks Erica!

Karen

---

**From:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>

**Sent:** Thursday, June 04, 2020 1:41 PM

**To:** White, Erica <Erica.White@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** RE: Governor of Oregon - Department R/C

Hi Erica,

My supervisor says that's a great idea and that it would be acceptable.

Thank you,  
Stephanie

---

**From:** White, Erica <Erica.White@fda.hhs.gov>

**Sent:** Thursday, June 4, 2020 12:37 PM

**To:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** FW: Governor of Oregon - Department R/C

Hi Stephanie,

In lieu of a letter, would it be acceptable to do a phone call with Oregon? This may be a quicker way of getting the Governor's questions answered.

Thanks,

Erica

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

**Sent:** Thursday, June 04, 2020 12:05 PM

**To:** White, Erica <Erica.White@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** RE: Governor of Oregon - Department R/C

Hi Erica,

Sorry, I am still working on it. OL has asked us to prioritize several letters (two of which are responses to oversight letters where the Committee may make additional statements publicly if they do not hear back from us), as well, so I am going to need at least another week to get this one finished. If we can get it done sooner, we will.

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>

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**From:** White, Erica <Erica.White@fda.hhs.gov>

**Sent:** Thursday, June 4, 2020 12:04 PM

**To:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** RE: Governor of Oregon - Department R/C

Hi Jennifer,

Checking on the status of this request?

Erica

---

**From:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>

**Sent:** Monday, June 1, 2020 1:50 PM

**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>

**Subject:** RE: Governor of Oregon - Department R/C

From the email, it seems it's because they're COVID correspondences and we've (the Agency) had them since March. They're also asking for the Porter + 83 member letter as well, so it's not just this one. Obviously the COVID ones are priority but I think the duration we've had them is also playing a role in their request.

Thank you,  
Stephanie

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

**Sent:** Monday, June 1, 2020 1:40 PM

**To:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>

**Subject:** RE: Governor of Oregon - Department R/C

I'll see what I can do. Any idea why they removed the hold?

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>

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**From:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Sent:** Monday, June 1, 2020 1:39 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C  
**Importance:** High

Good afternoon ladies,

I hate to bother you but the Department just wrote in and is requesting the response for this letter. They've removed the hold and it is therefore due as soon as possible.

Do you have an idea as to when I can receive the response to have the Commissioner take a look before sending it to the Department?

Thank you,  
Stephanie

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**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Sent:** Thursday, May 28, 2020 10:45 AM  
**To:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Hi Stephanie,

No updates on this. Sorry.

Best,

Jennifer

---

**From:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Sent:** Thursday, May 28, 2020 10:45 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Good morning everyone,

I hope this short week hasn't been too hectic.

Are there any updates to report on this one?

Thank you,  
Stephanie

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 12:02 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Good morning Jennifer,

Checking on the status of this request.

Erica

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**From:** White, Erica  
**Sent:** Monday, May 11, 2020 5:21 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Hi Jennifer,

Following up on this request.

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

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**From:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Date:** May 5, 2020 at 2:08:50 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>, Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Hi sorry, will try to get this done soon.

**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>

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Tuesday, May 5, 2020 2:08 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** RE: Governor of Oregon - Department R/C

Hi Jennifer,

Checking on the status of this request.

Erica

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**From:** White, Erica  
**Sent:** Tuesday, April 28, 2020 1:19 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>  
**Subject:** FW: Governor of Oregon - Department R/C

Hi Jennifer,

Do you have an update on the status of this request.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** White, Erica

**Sent:** Thursday, April 2, 2020 4:20 PM

**To:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>

**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>

**Subject:** FW: Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Good afternoon everyone,

FDA has been asked to prepare a response to Governor Kate Brown who writes about Oregon's need for sufficient personal protective equipment (PPE) and ventilators to assist with the COVID-19 epidemic. IGA has drafted an initial response. CDRH and the JIC, please review and clear the attached draft by COB, Monday, April 6.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

Erica.White@fda.hhs.gov



**From:** aimssystem@fda.hhs.gov <aimssystem@fda.hhs.gov>

**Sent:** Thursday, April 2, 2020 7:21 AM

**To:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Elwood, Will <William.Elwood@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>

**Subject:** Referral from FDA/OC/OES/ on Correspondence Control # 2020-1492

Note: Do NOT reply directly to this E-mail

A referral has been sent to your office by FDA/OC/OES/ on Correspondence Control # 2020-1492 requesting your assistance. A summary of the referral appears below. If you have any questions, please contact WANDA G. RUSS of FDA/OC/OES/.

Action:

Due Date:

Synopsis:

**Prepare Response for  
Signature**

**Tuesday, April 7, 2020**

**Department D/R for  
Commissioner Sig and  
Department R/C Governor  
Brown writes about**

**Oregon's need for sufficient personal protective equipment (PPE) and ventilators to assist with the COVID-19 epidemic.**

Please click the URL below to access the referral:

[http://aims.fda.gov/cktoken/ct\\_token.mainPage?p\\_token=sg8h1r70j03k570c3cm00000gzqfu60000158rjbmmgyp82330luis283r589ern](http://aims.fda.gov/cktoken/ct_token.mainPage?p_token=sg8h1r70j03k570c3cm00000gzqfu60000158rjbmmgyp82330luis283r589ern)

You can view the original correspondence by clicking the button 'View Orig Corr' (if available). After reviewing all the information provided, please acknowledge receipt of the referral by clicking either the ACCEPT button or the DECLINE button.

If you ACCEPT the referral, a new COMPLETE button is immediately displayed. You can either:

Click the COMPLETE button to complete the referral now

OR

You MUST retain this e-mail with the above URL until you have completed the referral request. Click the above URL again and click the COMPLETE button.

---

**Sent:** 6/18/2020 1:16:11 PM  
**Subject:** FW: New Question from PENNSYLVANIA re: N95 Masks

Hi Karen,

Below is my proposed response to Brian.

(b)(5)

**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Wednesday, June 17, 2020 3:53 PM  
**To:** Watson, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** FW: [External] More information about your Inquiry - China-Manufactured N95 Masks

Hello again Ruth.....my coworker chimed in with this below...if you can shed some light, that would be great!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

---

**From:** Fogarty, Jamon <jafogarty@pa.gov>  
**Sent:** Wednesday, June 17, 2020 3:39 PM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Cc:** Knerr, Gregory R <gknerr@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

One of the suppliers I've been speaking with sent me a link to the EUA which, on page 2, contains a link to a Certified Equipment List for respirators: [https://www2a.cdc.gov/drds/cel/cel\\_results.asp?startrecord=1&Search=cel form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=](https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel%20form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=)

Unfortunately, I can't tell if or how this list differs from the main NIOSH website we were looking at during our call. It also still leaves the question, why are certain masks identified as "surgical" by the FDA on the NIOSH website?

Here is the link to the EUA if you're interested: <https://www.fda.gov/media/135763/download>

**Jamon L. Fogarty** | Associate Commodity Manager  
PA Department of General Services  
Bureau of Procurement  
Phone: 717.214.9723 | Fax: 717.346.3820  
[www.dgs.state.pa.us/procurement](http://www.dgs.state.pa.us/procurement)

---

**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Wednesday, June 17, 2020 2:18 PM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** Fogarty, Jamon <jafogarty@pa.gov>; Knerr, Gregory R <gknerr@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Well, hello again Ruth

I am copying 2 co-workers of mine on this email who have been very involved in our N95 sourcing effort.

We have a question....for acceptable N95s cleared under the FDA EUA, are these the ones on the link below or is there another list.

[https://www.cdc.gov/niosh/npptl/topics/respirators/disp\\_part/resource3surgicaln95.html](https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/resource3surgicaln95.html)

Jamon, feel free to expound on this, etc....

Thanks Ruth for your continued support!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

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**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Thursday, June 11, 2020 9:40 AM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

You, too, Brian.

If you ever have any questions, or issues getting answers (at least from FDA!), please let me know – I will be happy to assist any way I can!

Take care and be well!

Ruth

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**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Tuesday, June 09, 2020 4:47 PM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Excellent...thanks a bunch, Ruth.

I can't tell you how refreshing it is to connect with someone who has answers and is responsive.

I really appreciate this!

Continue to be safe!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

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**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Tuesday, June 9, 2020 3:36 PM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Cc:** Restagno, Victor <vrestagno@pa.gov>; White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Good to hear from you, Brian. I am fine, and hope you, too, are doing well!

I've found some preliminary info that might be helpful:

- One is an FDA slide deck ("Testing Supply Substitution Strategies" - copy attached also). Starting at slide 3, there is information about specimen collection, including some info about swabs.
- The second is a Q&A webpage on the CDRH (Center for Diagnostics and Radiological Health) website; about half-way through, there are two sections of Q&A that might be helpful to you – both discuss standards for swabs: one is labeled "**What If I Do Not Have...? Testing Supply Substitution Strategies**" followed by "**Specimen**

**Collection,”** and just below that, you’ll see some Q&A on “**3D Printed Swab FAQs**” (while you might not be specifically interested in 3D-printed swabs, there’s some relevant info that’s applicable to swabs generally).

FYI - It appears that “swabs” are referred to in FDA regulations as “Absorbent Tipped Applicators” and are regulated as Class 1 medical devices under 21 CFR 880.6025.

My colleague, Erica White, on the FDA Intergovernmental Affairs (IGA) staff is checking with CDRH for any other information that might help you, and will follow up with you by email. I’ve cc’d Erica here, so that you have her contact info going forward (I’ve also cc’d Karen Meister, who’s the acting Director of IGA). I’m sure that Erica will find out if there is any other CDRH guidance on standards for swabs used for testing.

Best regards!

Ruth

**Ruth G. Watson**

*Congressional Affairs Specialist*

Office of Legislation  
U.S. Food and Drug Administration  
Office: 301-796-8927 / Mobile: 301-219-4162  
ruth.gras@fda.hhs.gov

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**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Tuesday, June 09, 2020 9:28 AM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** Restagno, Victor <vrestagno@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Greetings Ruth,  
Hope all is going well.  
Is there any FDA guidance on nasal swabs? By guidance, I mean approved mfgs, standards (ASTM or other) for compliance, etc  
Been searching the site, but not finding anything relevant.

Would appreciate any info you might have.

Thanks very much,  
**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

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**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Friday, May 8, 2020 11:13 AM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Subject:** [External] More information about your Inquiry - China-Manufactured N95 Masks

**ATTENTION:** *This email message is from an external sender. Do not open links or attachments from unknown sources. To report suspicious email, forward the message as an attachment to CWOPA\_SPAM@pa.gov.*

Hello Brian,

Here is additional background information about the N95 mask issue, that might be helpful to you and your colleagues in PA. I will respond further on the separate KN95 mask issue.

Ruth

On May 7, FDA issued a revised Emergency Use Authorization for disposable filtering facepiece respirators manufactured in China that do not meet NIOSH standards. FDA is concerned that certain filtering facepiece respirators manufactured in China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19. These concerns are based on test results from the National Institute for Occupational Safety and Health (NIOSH) showing that some of these respirators did not meet the expected performance criteria of greater than or equal to 95 percent particulate efficiency. The revised EUA includes an updated appendix that lists the respirators that have been authorized for use in health care settings by health care providers (HCPs) to prevent exposure to SARS-CoV-2. The appendix was updated to remove certain respirators that are no longer authorized under the EUA.

FDA today also issued a Letter to Health Care Providers, which describes:

- Changes to the FDA's Emergency Use Authorization for respirators manufactured in China and removal of some of these respirators from the Appendix listing authorized respirators.
- Considerations for health care organizations when using or purchasing respirators.
- Actions the FDA has taken to help ensure the quality of respirators.
- Instructions for reporting problems with respirators to the FDA.

**Additional Resources:**

- [FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic](#)



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**To:** Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]  
**Subject:** RE: Request for Input for 18 June Update on FDA 2019-nCoV SITREP

John Fish of USDVA – requested an FDA inspection rep to meet a shipment of PPE mask donation that USDVA will be accepting.

Brian Vulgaris of PA

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**From:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Sent:** Thursday, June 18, 2020 2:32 PM  
**To:** IGA Staff <IGASStaff@fda.hhs.gov>  
**Subject:** Request for Input for 18 June Update on FDA 2019-nCoV SITREP

IGA Team- Just a reminder to send me any COVID-related items for today's SIT report by 2:30. Thanks! Chris

Christopher C. Campbell, M.A.  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Christopher.Campbell@fda.hhs.gov



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**From:** Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>  
**Sent:** Wednesday, June 17, 2020 9:29 AM  
**To:** Nguyen, Michael A. <Michael.Nguyen1@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>  
**Subject:** FW: Request for Input for 17 June Update on FDA 2019-nCoV SITREP

Good morning!

Please provide any updates to me by 2:45 pm today.

Thanks!

Caitlin

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**From:** Measer, Gregory <Gregory.Measer@fda.hhs.gov>  
**Sent:** Wednesday, June 17, 2020 9:26 AM  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <AlfredMignone@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Hall, Valerie <Valerie.Hall@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Lucas, Tanisha <Tanisha.Lucas@fda.hhs.gov>; Gutierrez, Sacha <Sacha.Gutierrez@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Arsenault, Sam <Samuel.Arsenault@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Jackson, LeeAnne

<LeeAnne.Jackson@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Gindes, Melinda F <Melinda.Gindes@fda.hhs.gov>; Harrison, Tina <Tina.Harrison@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Newkirk, Ryan <Ryan.Newkirk@fda.hhs.gov>; Berrellez, Jessica <Jessica.Berrellez@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Montgomery, Alfred <Alfred.Montgomery@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Steffen, Scott E <Scott.Steffen@fda.hhs.gov>; CDRH\_ARC\_IMGRep <CDRH\_ARC\_IMGRep@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Pittman, Eric <Eric.Pittman@fda.hhs.gov>; Livsey, Kimberly <Kimberly.Livsey@fda.hhs.gov>

**Cc:** FDA Emergency Operations <emergency.operations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; CVM IMG ERCS <CVMIMGERCS@fda.hhs.gov>

**Subject:** Request for Input for 17 June Update on FDA 2019-nCoV SITREP

Hi All,

Attached for reference is the 16 June SITREP on the FDA response to the 2019-nCoV outbreak.

**Please provide any new updates, or let me know if you do not have new updates, by 3:30 PM.**

Please highlight any info that should not be shared outside of FDA in red.

Thank you for your continued assistance with this effort. Let me know if you have any questions or concerns.

Best,

Greg

**Gregory Measer, JD**

*Regulatory Counsel*

Office of Counterterrorism and Emerging Threats  
Office of the Chief Scientist, Office of the Commissioner  
U.S. Food and Drug Administration  
202-774-4146 / Gregory.Measer@fda.hhs.gov



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**From:** Erica.White@fda.hhs.gov [Erica.White@fda.hhs.gov]  
**Sent:** 6/19/2020 6:49:33 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** Fwd: Coronavirus (COVID-19) Update: Daily Roundup June 19, 2020

Thank you,

### **Coronavirus (COVID-19) Update:**

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- The FDA issued an updated [FDA COVID-19 Response At-A-Glance Summary](#) that provides a quick look at facts, figures, and highlights of the agency's response efforts.
- The FDA continues to take creative and flexible approaches to address access to critical medical products in response to COVID-19. In partnership with academic researchers, non-traditional manufacturers, communities of makers, and individuals who are banding together to support and fill local and national needs, the FDA is actively engaged and is developing ways to support these groups seeking to help their communities. Our goal is to help expand the availability of relevant products in ways that are consistent with the FDA's public-health mission.

For example, the FDA is working in partnership with the National Institutes of Health (NIH), the Veterans Administration (VA), and America Makes to support non-traditional manufacturing approaches (e.g., 3D printing), to address device shortages including personal protective equipment (PPE). Through this partnership, 3D-printable designs for COVID response are assessed by the VA, and the NIH posts them on its 3D Print Exchange. The FDA has, among other things, provided information on labeling and testing for face shields and face masks. Today, the FDA web update documents how this partnership has contributed to the number of medical devices — including PPE — and parts available to support the COVID-19 response since its launch 10 weeks ago. For example, 31 community-submitted designs passed the testing performed by VA clinics and were given clinically reviewed status. In addition, this effort has so far matched more than 272,000 3D-printed face shields and more than 230,000 3D-printed face masks with health care providers and others in need. The FDA has issued a [temporary policy](#) for face masks and respirators during the COVID-19 public-health emergency.

- On Tuesday, June 23, 12:00–1:00 pm ET, the FDA, along with the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA), will host the second webinar in the respirator webinar series on the topic of Importing Respirators for Health Care Personnel Use during COVID-19 Pandemic.
- The FDA updated its guidance, titled [Notifying CDRH of a Permanent Discontinuance or Interruption in Manufacturing of a Device Under Section 506J of the FD&C Act During the COVID-19 Public Health Emergency](#), to facilitate notification regarding device manufacturing interruptions or discontinuances. The FDA updated this guidance to include a list of device types and corresponding product codes that FDA recommends manufacturers consider in determining whether a notification under Section 506J of the FD&C Act is required during the COVID-19 pandemic. The CARES Act, which added Section 506J to the FD&C Act, is an important step that advances FDA's ability to prevent or mitigate potential medical device shortages during a public health emergency.
- FDA issued a [guidance](#) that provides recommendations to pharmaceutical manufacturers on actions to take when an employee who has been directly involved in manufacturing drugs has a confirmed infection of COVID-19, symptoms of COVID-19, or has been exposed to an infected person. FDA's recommendations are intended to help avoid negative effects on the safety and quality of drugs. FDA expects drug manufacturers to evaluate existing manufacturing controls to prevent drug safety or quality issues related to contamination from SARS-CoV-2. Drug manufacturers should also review CDC guidance regarding when employees may continue working following exposure or potential exposure to COVID-19 as well as procedures to minimize exposure and transmission in the workplace. FDA is not aware of any drugs that have been contaminated with SARS-CoV-2 or of information indicating transmission of COVID-19 is associated with drugs.

- The FDA issued a warning letter to one company for selling fraudulent COVID-19 products, as part of the agency's effort to protect consumers. The warned company, Project 1600, Inc., offers cannabidiol (CBD) products for sale in the United States with misleading claims that the products can mitigate, prevent, treat, or cure COVID-19 in people. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
- The FDA issued a Letter to Clinical Laboratory Staff and Health Care Providers recommending that they stop using COVID-19 antibody tests that are listed on the FDA's "removed" test list. The "removed" test list includes tests in which significant clinical performance problems were identified that cannot be or have not been addressed by the commercial manufacturer in a timely manner, tests for which an Emergency Use Authorization request has not been submitted by a commercial manufacturer of a serology test within a reasonable period of time as outlined in the FDA's guidance, and tests voluntarily withdrawn by the respective commercial manufacturers.
- Testing updates:
  - To date, the FDA has authorized 144 tests under EUAs; these include 122 molecular tests, 21 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 6/19/2020 6:58:25 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 19, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

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**Additional Resources:**

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- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 6/22/2020 7:46:43 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 22, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- The FDA issued a guidance document, titled "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices - Questions and Answers," with answers to frequently asked questions. These include answers concerning certain aspects of sponsor requests for formal meetings with the FDA, user-fee application goals and timelines, and other regulatory and policy issues related to device development for the duration of the COVID-19 public health emergency.
- As part of the FDA's continuing effort to protect consumers, the agency issued a warning letter to one firm for selling fraudulent COVID-19 products. The seller, North Isle Wellness Center, offers Methylene Blue products for sale in the United States with misleading claims that the products can mitigate, prevent, treat, or cure COVID-19 in people. The letter requests that the seller take immediate action to cease the sale of such unapproved and unauthorized products. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider.
- Testing updates:
  - To date, the FDA has authorized 145 tests under EUAs; these include 122 molecular tests, 22 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)



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**Sent:** 6/23/2020 10:07:39 AM  
**To:** Vulgaris, Brian [bvulgaris@pa.gov]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

Good morning Brian,

Thank you for this email. I am glad to put together a call to help you get your questions answered. If you let me know your specific questions, this will help ensure we have the appropriate people on the call.

I also wanted to let you know that today, from 12:00 pm - 1:00 pm ET, the FDA, along with the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA), will host the second webinar in the webinar series on the topic of Importing Respirators for Health Care Personnel Use during COVID-19 Pandemic. This webinar may answer some of the questions you have. More information about the webinar can be found at this link: <https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-series-respirators-health-care-personnel-use-during-covid-19-pandemic-06232020-06232020#event-information>

Hopefully the webinar will be helpful. If you still have questions, please let me know and I will put together a call.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



---

**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Tuesday, June 23, 2020 10:04 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

Thanks Erica,  
Would you be open to a skype call with some of my colleagues on this?

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914

Phone: 717.214.9506

**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

---

**From:** White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>

**Sent:** Thursday, June 18, 2020 2:04 PM

**To:** Vulgaris, Brian <[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)>

**Cc:** Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>

**Subject:** [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

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Good afternoon Brian,

Thank you for your email below about face masks. N95 respirators and surgical masks are examples of personal protective equipment that are used to protect the wearer from airborne particles and from liquid contaminating the face.

Masks and respirators both cover a wearer's nose and mouth, but they differ in several aspects. Masks are loose fitting and may not provide full protection from breathing in airborne pathogens, such as viruses.

- **Face masks (non-surgical masks)** may not provide protection from fluids or may not filter particles, needed to protect against pathogens, such as viruses. They are not for surgical use and are not considered personal protective equipment.
- **Surgical masks** are fluid-resistant, disposable, and loose-fitting devices that create a physical barrier between the mouth and nose of the wearer and the immediate environment. They are for use in surgical settings and do not provide full protection from inhalation of airborne pathogens, such as viruses.

Respirators are personal protective equipment that tightly fit the face and filter airborne particles to protect health care workers. They provide a higher level of protection against viruses and bacteria when properly fit-tested. This document does not address respirators.

This CDC infographic explains the differences between surgical masks and N95 respirators.

Hopefully this has been helpful. More information can also be found on our webpage FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-3309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Wednesday, June 17, 2020 3:53 PM  
**To:** Watson, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** FW: [External] More information about your Inquiry - China-Manufactured N95 Masks

Hello again Ruth.....my coworker chimed in with this below...if you can shed some light, that would be great!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**bvulgaris@pa.gov**

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**From:** Fogarty, Jamon <jafogarty@pa.gov>  
**Sent:** Wednesday, June 17, 2020 3:39 PM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Cc:** Knerr, Gregory R <gknerr@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

One of the suppliers I've been speaking with sent me a link to the EUA which, on page 2, contains a link to a Certified Equipment List for respirators: [https://www2a.cdc.gov/drds/cel/cel\\_results.asp?startrecord=1&Search=cel form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=](https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=)

Unfortunately, I can't tell if or how this list differs from the main NIOSH website we were looking at during our call. It also still leaves the question, why are certain masks identified as "surgical" by the FDA on the NIOSH website?

Here is the link to the EUA if you're interested: <https://www.fda.gov/media/135763/download>

**Jamon L. Fogarty** | Associate Commodity Manager  
PA Department of General Services  
Bureau of Procurement  
Phone: 717.214.9723 | Fax: 717.346.3820  
[www.dgs.state.pa.us/procurement](http://www.dgs.state.pa.us/procurement)

---

**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Wednesday, June 17, 2020 2:18 PM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** Fogarty, Jamon <jafogarty@pa.gov>; Knerr, Gregory R <gknerr@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Well, hello again Ruth  
I am copying 2 co-workers of mine on this email who have been very involved in our N95 sourcing effort.

We have a question....for acceptable N95s cleared under the FDA EUA, are these the ones on the link below or is there another list.

[https://www.cdc.gov/niosh/npptl/topics/respirators/disp\\_part/respsource3surgicaln95.html](https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3surgicaln95.html)

Jamon, feel free to expound on this, etc....

Thanks Ruth for your continued support!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

---

**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Thursday, June 11, 2020 9:40 AM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

You, too, Brian.

If you ever have any questions, or issues getting answers (at least from FDA!), please let me know – I will be happy to assist any way I can!

Take care and be well!

Ruth

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**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Tuesday, June 09, 2020 4:47 PM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Excellent...thanks a bunch, Ruth.

I can't tell you how refreshing it is to connect with someone who has answers and is responsive.

I really appreciate this!

Continue to be safe!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

---

**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Tuesday, June 9, 2020 3:36 PM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Cc:** Restagno, Victor <vrestagno@pa.gov>; White, Erica <Erica.White@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Good to hear from you, Brian. I am fine, and hope you, too, are doing well!

I've found some preliminary info that might be helpful:

- One is an FDA slide deck ("Testing Supply Substitution Strategies" - copy attached also). Starting at slide 3, there is information about specimen collection, including some info about swabs.
- The second is a Q&A webpage on the CDRH (Center for Diagnostics and Radiological Health) website; about half-way through, there are two sections of Q&A that might be helpful to you – both discuss standards for swabs: one is labeled "**What If I Do Not Have...? Testing Supply Substitution Strategies**" followed by "**Specimen Collection,**" and just below that, you'll see some Q&A on "**3D Printed Swab FAQs**" (while you might not be specifically interested in 3D-printed swabs, there's some relevant info that's applicable to swabs generally).

FYI - It appears that "swabs" are referred to in FDA regulations as "Absorbent Tipped Applicators" and are regulated as Class 1 medical devices under 21 CFR 880.6025.

My colleague, Erica White, on the FDA Intergovernmental Affairs (IGA) staff is checking with CDRH for any other information that might help you, and will follow up with you by email. I've cc'd Erica here, so that you have her contact info going forward (I've also cc'd Karen Meister, who's the acting Director of IGA). I'm sure that Erica will find out if there is any other CDRH guidance on standards for swabs used for testing.

Best regards!

Ruth

Ruth G. Watson

*Congressional Affairs Specialist*

Office of Legislation

U.S. Food and Drug Administration

Office: 301-796-8927 / Mobile: (b)(6)

ruth.gras@fda.hhs.gov

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**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Tuesday, June 09, 2020 9:28 AM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** Restagno, Victor <vrestagno@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Greetings Ruth,

Hope all is going well.

Is there any FDA guidance on nasal swabs? By guidance, I mean approved mfgs, standards (ASTM or other) for compliance, etc

Been searching the site, but not finding anything relevant.

Would appreciate any info you might have.

Thanks very much,

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

---

**From:** Gras, Ruth <[Ruth.Gras@fda.hhs.gov](mailto:Ruth.Gras@fda.hhs.gov)>

**Sent:** Friday, May 8, 2020 11:13 AM

**To:** Vulgaris, Brian <[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)>

**Subject:** [External] More information about your Inquiry - China-Manufactured N95 Masks

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Hello Brian,

Here is additional background information about the N95 mask issue, that might be helpful to you and your colleagues in PA. I will respond further on the separate KN95 mask issue.

Ruth

On May 7, FDA issued a revised Emergency Use Authorization for disposable filtering facepiece respirators manufactured in China that do not meet NIOSH standards. FDA is concerned that certain filtering facepiece respirators manufactured in China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19. These concerns are based on test results from the National Institute for Occupational Safety and Health (NIOSH) showing that some of these respirators did not meet the expected performance criteria of greater than or equal to 95 percent particulate efficiency. The revised EUA includes an updated appendix that lists the respirators that have been authorized for use in health care settings by health care providers (HCPs) to prevent exposure to SARS-CoV-2. The appendix was updated to remove certain respirators that are no longer authorized under the EUA.

FDA today also issued a Letter to Health Care Providers, which describes:

- Changes to the FDA's Emergency Use Authorization for respirators manufactured in China and removal of some of these respirators from the Appendix listing authorized respirators.
- Considerations for health care organizations when using or purchasing respirators.
- Actions the FDA has taken to help ensure the quality of respirators.
- Instructions for reporting problems with respirators to the FDA.

**Additional Resources:**

- [FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic](#)

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**Sent:** 6/23/2020 10:18:33 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

Thanks. When I searched, I did find the one your sent; however, you indicated there was one for PPE. The one you sent is for diagnostic testing, whereas the question below relates to masks. Is there one related to PPE that I can send him?

Thanks,

Erica

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, June 23, 2020 10:13 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

<https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/medical-device-webinars-and-stakeholder-calls>

I googled Town Hall June 23, 2020, on FDA webpage. Hope this helps.  
Thanks Erica.

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Tuesday, June 23, 2020 10:11 AM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

For some reason I can't find any information on that townhall. Can you tell me where you found it at?

Erica

---

**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Tuesday, June 23, 2020 10:07 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

Maybe tell him about the Town hall today!

---

**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Tuesday, June 23, 2020 10:04 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

Thanks Erica,  
Would you be open to a skype call with some of my colleagues on this?

**Brian Vulgaris** | Quality Assurance Supervisor

Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)

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**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Thursday, June 18, 2020 2:04 PM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** [External] RE: More information about your Inquiry - China-Manufactured N95 Masks

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Masks and respirators both cover a wearer's nose and mouth, but they differ in several aspects. Masks are loose fitting and may not provide full protection from breathing in airborne pathogens, such as viruses.

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This CDC infographic explains the differences between surgical masks and N95 respirators.

Hopefully this has been helpful. More information can also be found on our webpage FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)







---

**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Wednesday, June 17, 2020 3:53 PM  
**To:** Watson, Ruth <Ruth.Gras@fda.hhs.gov>  
**Subject:** FW: [External] More information about your Inquiry - China-Manufactured N95 Masks

Hello again Ruth.....my coworker chimed in with this below...if you can shed some light, that would be great!

**Brian Vulgaris** | Quality Assurance Supervisor  
Department of General Services | Bureau of Procurement  
Forum Place 6<sup>th</sup> Floor | 555 Walnut St  
Harrisburg, PA 17101-1914  
Phone: 717.214.9506  
**[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)**

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**From:** Fogarty, Jamon <jafogarty@pa.gov>  
**Sent:** Wednesday, June 17, 2020 3:39 PM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Cc:** Knerr, Gregory R <gknerr@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

One of the suppliers I've been speaking with sent me a link to the EUA which, on page 2, contains a link to a Certified Equipment List for respirators: [https://www2a.cdc.gov/drds/cel/cel\\_results.asp?startrecord=1&Search=cel form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=](https://www2a.cdc.gov/drds/cel/cel_results.asp?startrecord=1&Search=cel+form&maxrecords=50&schedule=84A&appdatefrom=&appdateto=&facepiecetype=Filtering+Facepiece&facepiecetype=Full+Facepiece&facepiecetype=Half+Mask&facepiecetype=Quarter+Mask&powered=&scbatype=&scbause=&privatelabel=)

Unfortunately, I can't tell if or how this list differs from the main NIOSH website we were looking at during our call. It also still leaves the question, why are certain masks identified as "surgical" by the FDA on the NIOSH website?

Here is the link to the EUA if you're interested: <https://www.fda.gov/media/135763/download>

**Jamon L. Fogarty** | Associate Commodity Manager  
PA Department of General Services  
Bureau of Procurement  
Phone: 717.214.9723 | Fax: 717.346.3820  
[www.dgs.state.pa.us/procurement](http://www.dgs.state.pa.us/procurement)

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**From:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Sent:** Wednesday, June 17, 2020 2:18 PM  
**To:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Cc:** Fogarty, Jamon <jafogarty@pa.gov>; Knerr, Gregory R <gknerr@pa.gov>  
**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Well, hello again Ruth

I am copying 2 co-workers of mine on this email who have been very involved in our N95 sourcing effort.

We have a question...for acceptable N95s cleared under the FDA EUA, are these the ones on the link below or is there another list.

[https://www.cdc.gov/niosh/npptl/topics/respirators/disp\\_part/respsource3surgicaln95.html](https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource3surgicaln95.html)

Jamon, feel free to expound on this, etc....

Thanks Ruth for your continued support!

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**From:** Gras, Ruth <[Ruth.Gras@fda.hhs.gov](mailto:Ruth.Gras@fda.hhs.gov)>

**Sent:** Thursday, June 11, 2020 9:40 AM

**To:** Vulgaris, Brian <[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)>

**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

You, too, Brian.

If you ever have any questions, or issues getting answers (at least from FDA!), please let me know – I will be happy to assist any way I can!

Take care and be well!

Ruth

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**From:** Vulgaris, Brian <[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)>

**Sent:** Tuesday, June 09, 2020 4:47 PM

**To:** Gras, Ruth <[Ruth.Gras@fda.hhs.gov](mailto:Ruth.Gras@fda.hhs.gov)>

**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Excellent...thanks a bunch, Ruth.

I can't tell you how refreshing it is to connect with someone who has answers and is responsive.

I really appreciate this!

Continue to be safe!

**Brian Vulgaris** | Quality Assurance Supervisor  
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**From:** Gras, Ruth <[Ruth.Gras@fda.hhs.gov](mailto:Ruth.Gras@fda.hhs.gov)>

**Sent:** Tuesday, June 9, 2020 3:36 PM

**To:** Vulgaris, Brian <[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)>

**Cc:** Restagno, Victor <[vrestagno@pa.gov](mailto:vrestagno@pa.gov)>; White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>; Meister, Karen G <[Karen.Meister@fda.hhs.gov](mailto:Karen.Meister@fda.hhs.gov)>

**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Good to hear from you, Brian. I am fine, and hope you, too, are doing well!

I've found some preliminary info that might be helpful:

- One is an FDA slide deck ("Testing Supply Substitution Strategies" - copy attached also). Starting at slide 3, there is information about specimen collection, including some info about swabs.
- The second is a Q&A webpage on the CDRH (Center for Diagnostics and Radiological Health) website; about half-way through, there are two sections of Q&A that might be helpful to you – both discuss standards for swabs: one is labeled "**What If I Do Not Have...? Testing Supply Substitution Strategies**" followed by "**Specimen Collection,**" and just below that, you'll see some Q&A on "**3D Printed Swab FAQs**" (while you might not be specifically interested in 3D-printed swabs, there's some relevant info that's applicable to swabs generally).

FYI - It appears that "swabs" are referred to in FDA regulations as "Absorbent Tipped Applicators" and are regulated as Class 1 medical devices under 21 CFR 880.6025.

My colleague, Erica White, on the FDA Intergovernmental Affairs (IGA) staff is checking with CDRH for any other information that might help you, and will follow up with you by email. I've cc'd Erica here, so that you have her contact info going forward (I've also cc'd Karen Meister, who's the acting Director of IGA). I'm sure that Erica will find out if there is any other CDRH guidance on standards for swabs used for testing.

Best regards!

Ruth

Ruth G. Watson

*Congressional Affairs Specialist*

Office of Legislation

U.S. Food and Drug Administration

Office: 301-796-8927 / Mobile: 301-219-4162

[ruth.gras@fda.hhs.gov](mailto:ruth.gras@fda.hhs.gov)

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**From:** Vulgaris, Brian <[bvulgaris@pa.gov](mailto:bvulgaris@pa.gov)>

**Sent:** Tuesday, June 09, 2020 9:28 AM

**To:** Gras, Ruth <[Ruth.Gras@fda.hhs.gov](mailto:Ruth.Gras@fda.hhs.gov)>

**Cc:** Restagno, Victor <[vrestagno@pa.gov](mailto:vrestagno@pa.gov)>

**Subject:** RE: [External] More information about your Inquiry - China-Manufactured N95 Masks

Greetings Ruth,  
Hope all is going well.

Is there any FDA guidance on nasal swabs? By guidance, I mean approved mfgs, standards (ASTM or other) for compliance, etc  
Been searching the site, but not finding anything relevant.

Would appreciate any info you might have.

Thanks very much,

**Brian Vulgaris** | Quality Assurance Supervisor  
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**From:** Gras, Ruth <Ruth.Gras@fda.hhs.gov>  
**Sent:** Friday, May 8, 2020 11:13 AM  
**To:** Vulgaris, Brian <bvulgaris@pa.gov>  
**Subject:** [External] More information about your Inquiry - China-Manufactured N95 Masks

***ATTENTION:** This email message is from an external sender. Do not open links or attachments from unknown sources. To report suspicious email, forward the message as an attachment to [CWOPA\\_SPAM@pa.gov](mailto:CWOPA_SPAM@pa.gov).*

Hello Brian,

Here is additional background information about the N95 mask issue, that might be helpful to you and your colleagues in PA. I will respond further on the separate KN95 mask issue.

Ruth

On May 7, FDA issued a revised Emergency Use Authorization for disposable filtering facepiece respirators manufactured in China that do not meet NIOSH standards. FDA is concerned that certain filtering facepiece respirators manufactured in China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19. These concerns are based on test results from the National Institute for Occupational Safety and Health (NIOSH) showing that some of these respirators did not meet the expected performance criteria of greater than or equal to 95 percent particulate efficiency. The revised EUA includes an updated appendix that lists the respirators that have been authorized for use in health care settings by health care providers (HCPs) to prevent exposure to SARS-CoV-2. The appendix was updated to remove certain respirators that are no longer authorized under the EUA.

FDA today also issued a Letter to Health Care Providers, which describes:

- Changes to the FDA's Emergency Use Authorization for respirators manufactured in China and removal of some of these respirators from the Appendix listing authorized respirators.
- Considerations for health care organizations when using or purchasing respirators.
- Actions the FDA has taken to help ensure the quality of respirators.
- Instructions for reporting problems with respirators to the FDA.

**Additional Resources:**

- [FAQs on the EUAs for Non-NIOSH Approved Respirators During the COVID-19 Pandemic](#)

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 6/23/2020 5:54:40 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinoa@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hkllaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 23, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- In a new FDA Voices, titled [FDA maintains the pace of meeting its goals on applications for medical products during the pandemic](#), FDA Commissioner Stephen M. Hahn, M.D., explains that one of the challenges facing the FDA during the COVID-19 pandemic is how to ensure the timely reviews of medical product applications despite a surge in volume of work and practical constraints that may impact our ability to conduct on-site inspections. The FDA has maintained the same pace of meeting its goals on review of applications for medical products during the pandemic that it has maintained in recent years.
- The FDA is partnering with the Critical Path Institute (C-Path) and the National Institutes of Health's National Center for Advancing Translational Sciences (NCATS) on the [CURE Drug Repurposing Collaboratory \(CDRC\)](#). CDRC is a forum for the exchange of clinical practice data to inform potential new uses of existing drugs for areas of high unmet medical need, advancing research in these areas. CDRC will focus on capturing relevant real-world clinical outcome data through the FDA-NCATS CURE ID [platform](#). In a pilot project focused on COVID-19, CDRC will use data collected via the CURE ID platform to aggregate global clinician treatment experiences to identify existing drugs that demonstrate possible treatment approaches warranting further study.
- A Consumer Update, titled [Getting Smarter about Food Safety: The Pandemic and Lessons Learned](#), explains that throughout the COVID-19 pandemic, the experts at the FDA have learned valuable lessons that will help shape our work to create a more digital and transparent, as well as safer, food system for you and your family. In the coming weeks, the FDA will unveil the blueprint for the New Era of Smarter Food Safety, which lays out how we will use technology and modern approaches over the next decade to strengthen the ways we approach the safety of the nation's food supply, every day and in times of crisis.
- Testing updates:
  - To date, the FDA has authorized 145 tests under EUAs; these include 122 molecular tests, 22 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 6/24/2020 1:17:38 PM  
**To:** Patel, Bharti [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=933ead78c9584fc6bb322f739bdaf5bc-Patelb]  
**Subject:** RE: re: Final response to State Senator Weiner - re: MSM donation of convalescent plasma.  
**Attachments:** FDA Response Sen. Wiener 6 10 2020.pdf

Here you go.

Erica

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**From:** Patel, Bharti <Bharti.Patel@fda.hhs.gov>  
**Sent:** Wednesday, June 24, 2020 1:16 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** re: Final response to State Senator Weiner - re: MSM donation of convalescent plasma.

Hi Erica.

Would you have a final copy of the response to Sen. Weiner?

Thanks,  
Bharti



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**From:** Pennington, Caitlin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6D2D563DD0E741D3AFE78F94E75349A0-PENNINGTONC]  
**Sent:** 6/24/2020 3:39:25 PM  
**To:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**CC:** Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]  
**Subject:** FDA Office of Legislation Daily Report: Wednesday, June 24, 2020

## TODAY

Sen. Ted Cruz (R-TX) introduced legislation to allow States to approve the use of diagnostic tests during a public health emergency.

Sen. Gary Peters (D-MI) introduced legislation to increase reporting of, help mitigate potential shortages related to, and promote, accountability and transparency for pharmaceuticals and medical devices. He also introduced legislation to encourage domestic advanced manufacturing of critical drugs and devices in order to address economic, health, and security concerns, combat shortages of critical drugs and devices, and promote increased domestic diversification of, and independence from foreign reliance on, pharmaceutical and medical device supply chains.

Sen. Elizabeth Warren (D-MA) introduced legislation to amend the Public Health Service Act to establish an Emergency Office of Manufacturing for Public Health.

Rep. Jeff Fortenberry (R-NE) introduced legislation to provide for the acceleration of access to clinical therapies for the treatment of amyotrophic lateral sclerosis.

## FDA Briefings for Congress

- Senate HSGAC majority staff briefing on drug shortages

## Outreaches

- June 23: Coronavirus (COVID-19) Update: Daily Roundup June 23, 2020

## Media

- Rep. Susan Brooks (R-IN): Today at a @HouseCommerce hearing, I asked top public health officials about increasing public health funding at federal, state & local levels & safety of vaccines hopefully coming in the next few months. Thanks Dr. Fauci, @SteveFDA, @CDCDirector & @HHS\_ASH for your leadership!

## COMING UP

- 6/25 Sen. John Thune (R-SD) staff briefing on hand sanitizer legislation
- 6/26 Senate HELP staff briefing on COVID-19 EUAs
- 6/26 Senate HELP staff briefing on CDER/CBER/ORR COVID updates
- 6/30 Senate HELP Hearing: COVID-19: Update on Progress Toward Getting Safely Back to Work and Back to School; Commissioner Hahn will be testifying for the Agency
- 7/2 Senate PSI staff briefing on deeming rule
- 7/7 Senate PSI staff briefing on illegal online pharmacies and drug activity
- 7/7 House E&C Minority staff briefing on second wave project

*The Office of Legislation (OL), an office within the Office of Policy, Legislation, and International Affairs (OPLIA), directs and manages FDA's engagement with Congress. Please feel free to contact OL staff directly or via 301-796-8900 or*

*legislation@fda.hhs.gov. For matters specific to the congressional budget and appropriations process, please contact the Office of Congressional Appropriations (OCA) at oo-ofba-congressional-government@fda.hhs.gov.*

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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 6/24/2020 7:53:11 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hkllaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 24, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- Today, FDA launched the first "FDA Insight" podcast, featuring FDA Commissioner Stephen Hahn, M.D., and FDA Deputy Commissioner for Medical and Scientific Affairs Anand Shah, M.D., discussing FDA's COVID-19 efforts, including the drug development process for a COVID-19 treatment. Future FDA Insight podcasts will feature Hahn, Shah, and other FDA leaders' insights into issues facing the agency — including the COVID-19 pandemic and other emerging topics.
- FDA Commissioner Stephen Hahn, M.D., spoke at the German Marshall Fund's Brussels Forum 2020. This 15<sup>th</sup> edition of the forum, live-streamed/posted on YouTube, featured a 25-minute conversation with Dr. Hahn, moderated by Axios Health Care Editor Sam Baker.
- Today, U.S. Secretary of Agriculture Sonny Perdue and FDA Commissioner Stephen Hahn, M.D., issued the following joint USDA-FDA statement regarding food export restrictions pertaining to COVID-19:

The United States understands the concerns of consumers here domestically and around the world who want to know that producers, processors and regulators are taking every necessary precaution to prioritize food safety especially during these challenging times. However, efforts by some countries to restrict global food exports related to COVID-19 transmission are not consistent with the known science of transmission.

There is no evidence that people can contract COVID-19 from food or from food packaging. The U.S. food safety system, overseen by our agencies, is the global leader in ensuring the safety of our food products, including product for export.

- Testing updates:
  - To date, there are 149 currently-authorized tests under EUAs; these include 125 molecular tests, 23 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**Sent:** 6/25/2020 4:33:12 PM  
**To:** Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**CC:** Brown, Akeisha [Akeisha.Brown@fda.hhs.gov]  
**Subject:** Re: (b)(4)

I think he's including IGA since they are from a state, but I don't think there is a specific ask of us right now.

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** June 25, 2020 at 4:28:30 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Brown, Akeisha <Akeisha.Brown@fda.hhs.gov>  
**Subject:** FW: (b)(4)

Hi Erica- Not sure what the to do is. I haven't read this all yet.

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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Sent:** Thursday, June 25, 2020 2:06 PM  
**To:** Maisel, William <William.Maisel@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Subject:** FW: (b)(4)

Bill,

I'm adding Karen Meister given the letters from the South Dakota Governor's Office and the North Dakota Department of Homeland Security.

I'm okay with the approach. (b)(4) (b)(5)

(b)(4) (b)(5)

(b)(5)

Jeff

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**From:** Maisel, William <William.Maisel@fda.hhs.gov>  
**Sent:** Thursday, June 25, 2020 1:53 PM  
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Cc:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
**Subject:** (b)(4)

Jeff,

Please see direct contact of our review staff from North Dakota. I am forwarding the email to you and to Jennifer, and will defer to the two of you as to who/how a response is provided.

Second: (b)(5)

(b)(5)

Thanks

Bill

**William H. Maisel, MD, MPH**  
*Director, Office of Product Evaluation and Quality*  
*CDRH Chief Medical Officer*

Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
Tel: 301-796-5550  
william.maisel@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/cdrheustomerservice?ID=1000&S=E>

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**From:** Eydelman, Malvina B. <Malvina.Eydelman@fda.hhs.gov>  
**Sent:** Thursday, June 25, 2020 12:20 PM  
**To:** Maisel, William <William.Maisel@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>  
**Cc:** Hawthorn, Anne T. <Anne.Hawthorn@fda.hhs.gov>; Lee, James J. (CDRH) <James.J.Lee@fda.hhs.gov>  
**Subject:** FW: (b)(4)

Bill / Angie,

(b)(4)

This

(b)(4)

(b)(4)

The team has been working and reviewing the sponsor's information and

(b)(4)

(b)(4)

To date all of the Ambu bag squeezer type of devices do have alarms, except one that was granted and EUA very early in the process and was at the height of concerns regarding shortages. Mitigating risks to health by advising that a patient be continually monitored is not practical for a mass casualty situations and thus the team has favored alarms and alerts per the AAMI standard.

The team is continuing to review and work the with the sponsor. On June 24, the team sent an email to the sponsor detailing outstanding issues regarding the lack of alarms.

Please advise as to who should respond to the e-mail below.

Thanks,

Malvina

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**From:** Schulz, Cody J. <cjschulz@nd.gov>

**Sent:** Tuesday, June 23, 2020 4:17 PM

**To:** Eydelman, Malvina B. <Malvina.Eydelman@fda.hhs.gov>; Ryan, Michael J <Michael.Ryan@fda.hhs.gov>; Lee, James J (CDRH) <James.J.Lee@fda.hhs.gov>; Yao, Joshua <Joshua.Yao@fda.hhs.gov>

**Subject:** (b)(4)

Dear Dr. Eydelman, Mr. Ryan, Dr. Lee and Mr. Yao,

The State of North Dakota through its Department of Emergency Services respectfully requests that the United States Food & Drug Administration (FDA) approve the Emergency Use Authorization (EUA) for the production of the device used to [REDACTED] (b)(4) [REDACTED]

Our state has an acute need and desire to purchase these devices in order to address potential emergency equipment shortages created by the COVID-19 pandemic. We are also preparing for and mitigating against the effects of a possible second wave of COVID-19 – which may arrive before adequate National Stockpile supplies exist – and need to have plans in place and lifesaving equipment available, especially in the rural areas of our state, where significant logistical challenges exist. We understand that nearly identical devices have already received EUA, and we believe that the FDA’s approval of this request serves the public good to address shortage of supplies and provide our residents with lifesaving treatment options in the event that no other ventilator device is available.

We thank you for your consideration and timely action on this matter.

Sincerely,

**Cody Schulz**

*Director of Homeland Security*

701.328.8256 • [REDACTED] (b)(6) (m) • cjschulz@nd.gov • www.des.nd.gov





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**Sent:** 6/27/2020 4:25:35 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: FDA Certified Vendors and Products for COVID 19 testing

Good morning Karen,

Below is proposed text for an email to Nikki.

Good morning Nikki,

Thank you for your email regarding a list of COVID 19 testing that has been authorized by FDA. That list of companies that have received Emergency Use Authorizations (EUA) can be found at <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>

This EUA list includes FDA companies approved for both diagnostic and antibody testing.

Hopefully this is helpful. If you have any additional questions please let me know.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Nikki.Guilford@governor.ohio.gov <Nikki.Guilford@governor.ohio.gov>  
**Sent:** Monday, April 27, 2020 9:35 AM  
**To:** Shulman, Dan <Dan.Shulman@fema.dhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** FDA Certified Vendors and Products for COVID 19 testing

Good morning – can you direct me to a complete FDA list of certified vendors and products for COVID 19 TESTING?

Thank you.

Nikki Guilford  
State of Ohio Washington D.C. Director  
DeWine-Husted Administration

[Nikki.guilford@governor.ohio.gov](mailto:Nikki.guilford@governor.ohio.gov)

202-624-8458 (direct)

(b)(6) mobile

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**Sent:** 6/29/2020 7:29:46 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group  
(FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: EUA Status - COVID-19 Serological test

Hi Karen,

Based on Jennifer's email, I changed the email below. Please let me know if the highlighted section is okay.

Thanks.

Good morning Garrett,

**(b)(5)**

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



**From:** Garrett Wheat <GWheat@senate.michigan.gov>  
**Sent:** Monday, April 27, 2020 5:08 PM  
**To:** IGA <IGA@fda.hhs.gov>  
**Cc:** Ruth Johnson <RJohnson@senate.michigan.gov>  
**Subject:** EUA Status - COVID-19 Serological test

Hello,

I am writing to see if we can please get an update on the status of an EUA application for COVID-19 serological testing which was submitted and/or any general update on the timeline or process for these approvals.

I was able to speak with CDRH staff directly last month and directed this company to the covid19dx@fda.hhs.gov email and they were able to successfully submit their application for an EUA for serological testing on April 9, but have not received any update since. Their application information is below, we would appreciate any update on the status:

We filed for an EUA/Notify on April 9th (b)(4)  
Our PIN# is (b)(4)  
Our PCN# is (b)(4)  
Our Owner Operator # is (b)(4)  
Our US Agent Receipt Code is (b)(4)  
Product Code is (b)(4)

Please let me know if you have any questions.

Thank you,  
-Garrett

Garrett Wheat  
Chief of Staff  
State Senator Ruth Johnson  
Michigan, 14<sup>th</sup> District

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**Sent:** 6/29/2020 12:16:50 PM  
**To:** Annie.MCCOLAUGH@oregon.gov  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Conversation with FDA re: PPE and Ventilators  
**Attachments:** Incoming Letter from Gov. Brown.pdf

Good morning Annie,

Governor Brown wrote a letter to Vice President Pence and Health and Human Services Secretary Azar regarding the availability of personal protective equipment (PPE) and ventilators in the State of Oregon (see attached letter). As the agency tasked with the regulation of both PPE and ventilators, FDA has been asked to respond to that letter.

In lieu of a written response, FDA thought it would be more expedient to have a conversation with staff in the governor's office to address questions and concerns related to the availability of manufacturing standards and the specifications for additional manufacturers to make PPE and ventilators, or working with these companies to temporarily expedite the evaluation and approval process to make these items. Please let us know with whom we could set up such a call.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 6/29/2020 8:37:05 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6); emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hkllaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup June 29, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

## Coronavirus (COVID-19) Update: Daily Roundup

The U.S. Food and Drug Administration today continued to take action in the ongoing response to the COVID-19 pandemic:

- The FDA and the Federal Trade Commission (FTC) jointly issued a warning letter to Hong Kong-based SuperHealthGuard and Loyal Great International, Ltd., advising these companies to cease selling unapproved products online to customers in the United States with misleading claims that such products mitigate, prevent, treat, diagnose, or cure COVID-19 in people. The FDA's action is in support of its efforts to protect the public health. FTC's action enforces provisions of the FTC Act, 15 U.S.C. 41, prohibiting unsupported drug advertising claims. There are no drugs approved by the FDA to prevent or cure COVID-19 in people. FDA advised the companies to review their respective websites to ensure that they are not misleadingly representing unproven products as safe and effective for a COVID-19-related use. Failure to immediately correct the unapproved new drug and misbranding violations could result in legal action, including, without limitation, seizure and injunction. FDA is advising consumers not to purchase or use certain products that have not been approved, cleared, or authorized by FDA and that are being misleadingly represented as safe and/or effective for the treatment or prevention of COVID-19. Misbranded or unapproved new drugs are subject to detention and refusal of admission, if they are offered for importation into the United States. The list of firms that have received warning letters is located [here](#).
- FDA issued Emergency Use Authorizations (EUAs) for the following SARS-CoV-2 molecular diagnostic tests:
  - [Inform Diagnostics, Inc.: Inform Diagnostics SARS-CoV-2 RT-PCR Assay](#)
  - [Diagnostic Solutions Laboratory, LLC: DSL COVID-19 Assay](#)
- FDA added the following products to the list of authorized ventilators, ventilator tubing connectors, and ventilator accessories under the ventilator Emergency Use Authorization (EUA)
  - [Stewart & Stevenson Healthcare Technologies, LLC: Apollo ABVM emergency resuscitator](#)
  - [SAGICO USA, LLC: V2O SAGICO SYSTEM Ventilator](#)
- To date, the FDA has authorized 155 tests under EUAs; these include 130 molecular tests, 24 antibody tests, and 1 antigen test.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 6/30/2020 11:47:02 AM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines

Good morning,

The Intergovernmental Affairs team at the FDA wanted to bring to your attention that today, the FDA took important action to help facilitate the timely development of safe and effective vaccines to prevent COVID-19 by providing guidance with recommendations for those developing COVID-19 vaccines for the ultimate purpose of licensure. The guidance, which reflects advice the FDA has been providing over the past several months to companies, researchers, and others, describes the agency's current recommendations regarding the data needed to facilitate the manufacturing, clinical development, and approval of a COVID-19 vaccine.

More information about this announcement can be found below and at this link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-action-help-facilitate-timely-development-safe-effective-covid>

Hopefully this is helpful. If you have any questions please feel free to contact me.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



## Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines

Today, the U.S. Food and Drug Administration took important action to help facilitate the timely development of safe and effective vaccines to prevent COVID-19 by providing guidance with recommendations for those developing COVID-19 vaccines for the ultimate purpose of licensure. The guidance, which reflects advice the FDA has been providing over the past several months to companies, researchers, and others, describes the agency's current recommendations regarding the data needed to facilitate the manufacturing, clinical development, and approval of a COVID-19 vaccine.

"We recognize the urgent need to develop a safe and effective vaccine to prevent COVID-19 and continue to work collaboratively with industry, researchers, as well as federal, domestic, and international partners to accelerate these



efforts. While the FDA is committed to expediting this work, we will not cut corners in our decisions and are making clear through this guidance what data should be submitted to meet our regulatory standards. This is particularly important, as we know that some people are skeptical of vaccine development efforts,” said FDA Commissioner Stephen M. Hahn, M.D. “We have not lost sight of our responsibility to the American people to maintain our regulatory independence and ensure our decisions related to all medical products, including COVID-19 vaccines, are based on science and the available data. This is a commitment that the American public can have confidence in and one that I will continue to uphold.”

Vaccines have been highly effective in preventing a range of serious infectious diseases. The FDA has the scientific expertise to evaluate any potential COVID-19 vaccine candidate regardless of the technology used to produce or to administer the vaccine. This includes the different technologies such as DNA, RNA, protein and viral vectored vaccines being developed by commercial vaccine manufacturers and other entities.

“In this particular crisis in which there is so much at stake, we need to help expedite vaccine development as much as we can without sacrificing our standards for quality, safety, and efficacy. We firmly believe that transparency regarding the FDA’s current thinking about the scientific data needed to support approval of safe and effective COVID-19 vaccines will help build public confidence in the FDA’s evaluation process, which will be critical in ensuring their use,” said Peter Marks, M.D., Ph.D., director of the FDA’s Center for Biologics Evaluation and Research. “Right now, neither the FDA nor the scientific community can predict how quickly data will be generated from vaccine clinical trials. Once data are generated, the agency is committed to thoroughly and expeditiously evaluating it all. But make no mistake: the FDA will only approve or make available a COVID-19 vaccine if we determine that it meets the high standards that people have come to expect of the agency.”

The guidance published today, “Development and Licensure of Vaccines to Prevent COVID-19,” provides an overview of key considerations to satisfy requirements for chemistry, manufacturing and control, nonclinical and clinical data through development and licensure, and for post-licensure safety evaluation. Importantly, given the current understanding of SARS-CoV-2 immunology, the goal of development programs at this time should be to support traditional FDA approval by conducting studies to directly evaluate the ability of the vaccine to protect humans from SARS-CoV-2 infection and/or disease.

The FDA strongly encourages the inclusion of diverse populations in all phases of clinical development, including populations most affected by COVID-19, specifically racial and ethnic minorities, as well as adequate representation in late phase trials of elderly individuals and those with medical comorbidities. Sponsors are also encouraged to include studies in their development plans that would provide data to support use during pregnancy, as well as plan for pediatric assessments of safety and effectiveness.

The guidance also discusses the importance of ensuring that the sizes of clinical trials are large enough to demonstrate the safety and effectiveness of a vaccine. It conveys that the FDA would expect that a COVID-19 vaccine would prevent disease or decrease its severity in at least 50% of people who are vaccinated.

Additionally, after approval by the FDA, the safety of all vaccines, including a COVID-19 vaccine, continues to be closely monitored using various existing surveillance systems. The FDA may also require post-marketing studies to further assess known or potential serious risks.

The guidance also notes that, as more is learned about SARS-CoV-2 immunology and vaccine immune responses, consideration may be given to the FDA’s Accelerated Approval pathway for vaccine licensure. However, identification of an immune response or other measure that is reasonably likely to predict clinical benefit would be needed for a specific vaccine candidate to use of this pathway. Due to the current public health emergency, the guidance also addresses considerations regarding Emergency Use Authorization (EUA) of an investigational vaccine – making clear that an assessment regarding any potential EUA for a COVID-19 vaccine would be made on a case-by-case basis considering the target population, the characteristics of the product, and the totality of the relevant, available scientific evidence, including preclinical and human clinical study data on the product’s safety and effectiveness.

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 6/30/2020 11:47:02 AM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniiss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billioux@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palauhealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines

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**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

Erica.White@fda.hhs.gov



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**To:** marie.davis@gobiz.ca.gov  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**BCC:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]; Adams, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5e85f0b3354d407390178cef6bdf9035-Michelle.Ad]  
**Subject:** RE: GO-Biz: request for a contact

Good morning Marie,

It was a pleasure speaking to you this morning regarding your email about importing product components. More information about the entry process can be found at this link: <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/entry-process>. This page also contains information specifically about the entry submission process that maybe helpful.

For imports related to COVID-19, please visit <https://www.fda.gov/industry/import-program-food-and-drug-administration-fda/importing-covid-19-supplies>.

Hopefully this is helpful. If you have any additional questions please feel free to reach out.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
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**From:** Marie Davis <[marie.davis@gobiz.ca.gov](mailto:marie.davis@gobiz.ca.gov)>  
**Date:** June 30, 2020 at 3:16:07 PM PDT  
**To:** Solis, Dan <[Dan.Solis@fda.hhs.gov](mailto:Dan.Solis@fda.hhs.gov)>  
**Cc:** Kaina Pereira <[kaina.pereira@gobiz.ca.gov](mailto:kaina.pereira@gobiz.ca.gov)>, Carlos Valderrama <[Carlos.Valderrama@gobiz.ca.gov](mailto:Carlos.Valderrama@gobiz.ca.gov)>  
**Subject:** GO-Biz: request for a contact

Good afternoon Dan,

My name is Marie Davis and I work with Carlos Valderrama at the California Governor's Office of Business and Economic Development, who recommended I reach out to you with this request.

I connected this morning with Micronet ([www.micronet.com](http://www.micronet.com)), a memory storage device company that is diversifying to new products such as infrared thermometers. The company designs and assembles in Torrance, CA. The ask is for technical assistance on FDA regs for imports of their product components. Are you a good contact to put them in touch with or is there someone you know that would be well suited?

With gratitude,

**Marie Davis**

Senior Business Development Specialist

Governor's Office of Business and Economic Development

Office: (916) 322-0596 | Cell: (b)(6) (preferred)

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**Sent:** 7/1/2020 5:38:25 PM  
**To:** CBER Exec. Sec. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4316a5092d542bb8a28f9b8feb6a319-cberexecsec]  
**CC:** Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Good morning CBER Exec Sec,

Below are follow-up questions from Dr. Shahs participation in a COVID-19 webinar hosted by the National Conference of State Legislatures (NCSL) a few weeks ago. Any assistance you can provide with answering the questions is greatly appreciated. The suggested Center for a response is in parenthesis next to each question.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>  
**Sent:** Thursday, April 30, 2020 4:18 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Follow Up Questions from Vaccine Webinar

Good Afternoon Chris and Erica,

I first want to say a huge thanks for all you and your team has helped us with during this time. Below are the questions that came in for Dr. Shah during the webinar but we obviously didn't have time to get to all of them. Would you all be able to take a look and provide any answers that you can? Understandably you may not be able to answer all of them or if some are more directing our members to a resource to read up on we would welcome that. Let me know if you have any questions and thank you again for all you have done for our members and staff!

- It was reported that Oxford University is testing a vaccine that could be available by August of 2020, This would be an incredibly rapid turnaround for a vaccine. Do you feel this might in fact happen? (CBER)
- Even if an effective and safe vaccine is developed, how long would it take to produce and distribute it to large parts of the U.S. population? (CBER)
- What is the actual number of weeks or months on the fast track program? (CBER)
- What is the timeline for therapies? (CBER)

- What kind of outreach is used in the Latino Hispanic communities? (Not sure what they are asking, or whom this would go to?)
- Have there been challenges with participation of Hispanics and African Americans in the clinical trials, as often is the case with the development of other vaccines/medications? (CBER)
- Have there been any supply challenges on the use of existing medicines to treat and/or alleviate symptoms of Covid 19? Can you provide us an brief example of such? (CDER)
- After talking to some physicians on the ER front lines I have the following question: Is there any protocol (or upcoming protocol) for prophylactic use of medications for healthcare professionals dealing with COVID-19 patients? There is apparently a great deal of confusion among them about this. (CDER)

Thank You,

Haley Nicholson  
National Conference of State Legislatures  
Senior Policy Director, Health & Human Services  
State-Federal Affairs  
202-624-8662 (o)



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**Sent:** 7/1/2020 5:38:36 PM  
**BCC:** [dottie.ochoa@alaska.gov](mailto:dottie.ochoa@alaska.gov); [kip.knudson@alaska.gov](mailto:kip.knudson@alaska.gov); [liz.filmore@governor.alabama.gov](mailto:liz.filmore@governor.alabama.gov); [julia.pickle@governor.alabama.gov](mailto:julia.pickle@governor.alabama.gov); [Kendall.Marr@governor.arkansas.gov](mailto:Kendall.Marr@governor.arkansas.gov); [JDudinsky@dudinskyassociates.com](mailto:JDudinsky@dudinskyassociates.com); [gconger@az.gov](mailto:gconger@az.gov); [Katie.wheelermathews@wdc.ca.gov](mailto:Katie.wheelermathews@wdc.ca.gov); [eve.otoole@hklaw.com](mailto:eve.otoole@hklaw.com); [jason@turnberrysolutionsllc.com](mailto:jason@turnberrysolutionsllc.com); [eve.lieberman@state.co.us](mailto:eve.lieberman@state.co.us); [dan.desimone@ct.gov](mailto:dan.desimone@ct.gov); [sheila.grant@state.de.us](mailto:sheila.grant@state.de.us); [Katherine.Russo@eog.myflorida.com](mailto:Katherine.Russo@eog.myflorida.com); [Ben@potomacsouthllc.com](mailto:Ben@potomacsouthllc.com); [madeleine.bordallo@guam.gov](mailto:madeleine.bordallo@guam.gov); [kymberly.m.sparlin@hawaii.gov](mailto:kymberly.m.sparlin@hawaii.gov); [stephanie.groen@iowa.gov](mailto:stephanie.groen@iowa.gov); [bobbi-jo.meuleman@gov.idaho.gov](mailto:bobbi-jo.meuleman@gov.idaho.gov); [Andrew.mitzel@gov.idaho.gov](mailto:Andrew.mitzel@gov.idaho.gov); [Pat.Collier@illinois.gov](mailto:Pat.Collier@illinois.gov); [debbie@indianagr.com](mailto:debbie@indianagr.com); [Timothy.Graham@ks.gov](mailto:Timothy.Graham@ks.gov); [adam@vikingnav.com](mailto:adam@vikingnav.com); [Alicia.Williams@la.gov](mailto:Alicia.Williams@la.gov); [kevin.mccolaugh@state.ma.us](mailto:kevin.mccolaugh@state.ma.us); [tiffany.waddell@maryland.gov](mailto:tiffany.waddell@maryland.gov); [ariel.judah@maryland.gov](mailto:ariel.judah@maryland.gov); [bethany.beausang@maine.gov](mailto:bethany.beausang@maine.gov); [Linda.Pistner@maine.gov](mailto:Linda.Pistner@maine.gov); [Derek.Langhauser@maine.gov](mailto:Derek.Langhauser@maine.gov); [Michael.Perry@maine.gov](mailto:Michael.Perry@maine.gov); [Jeremy.Kennedy@maine.gov](mailto:Jeremy.Kennedy@maine.gov); [Brousseauj@michigan.gov](mailto:Brousseauj@michigan.gov); [SherryD2@michigan.gov](mailto:SherryD2@michigan.gov); [ReadingerP@michigan.gov](mailto:ReadingerP@michigan.gov); [sasha.bergman@state.mn.us](mailto:sasha.bergman@state.mn.us); [David.Bilger@governor.mo.gov](mailto:David.Bilger@governor.mo.gov); [annehall.brashier@govreeves.ms.gov](mailto:annehall.brashier@govreeves.ms.gov); [aschafer@mt.gov](mailto:aschafer@mt.gov); [lorea.stallard@nc.gov](mailto:lorea.stallard@nc.gov); [Jordan.Whichard@nc.gov](mailto:Jordan.Whichard@nc.gov); [jim.mccleskey@nc.gov](mailto:jim.mccleskey@nc.gov); [jabeehler@nd.gov](mailto:jabeehler@nd.gov); [Lauren.kintner@nebraska.gov](mailto:Lauren.kintner@nebraska.gov); [David.Bettencourt@nh.gov](mailto:David.Bettencourt@nh.gov); [Alexandria.Hermann@nj.gov](mailto:Alexandria.Hermann@nj.gov); [courtney.kerster@state.nm.us](mailto:courtney.kerster@state.nm.us); [khudak@cassidy.com](mailto:khudak@cassidy.com); [Aebiner@cassidy.com](mailto:Aebiner@cassidy.com); [Alexander.Cochran@exec.ny.gov](mailto:Alexander.Cochran@exec.ny.gov); [Nikki.Guilford@governor.ohio.gov](mailto:Nikki.Guilford@governor.ohio.gov); [Karla.Carpenter@Governor.Ohio.gov](mailto:Karla.Carpenter@Governor.Ohio.gov); [Samantha.Davidson@sos.ok.gov](mailto:Samantha.Davidson@sos.ok.gov); [Annie.MCCOLAUGH@oregon.gov](mailto:Annie.MCCOLAUGH@oregon.gov); [msnead@pa.gov](mailto:msnead@pa.gov); [jstoripan@prfaa.pr.gov](mailto:jstoripan@prfaa.pr.gov); [david.ortiz@governor.ri.gov](mailto:david.ortiz@governor.ri.gov); [JMarsh@governor.sc.gov](mailto:JMarsh@governor.sc.gov); [Kennedy.Noem@state.sd.us](mailto:Kennedy.Noem@state.sd.us); [Chris.Walker@tn.gov](mailto:Chris.Walker@tn.gov); [wes.hambrick@gov.texas.gov](mailto:wes.hambrick@gov.texas.gov); [teri.helenese@go.vi.gov](mailto:teri.helenese@go.vi.gov); [Gordonlarsen@utah.gov](mailto:Gordonlarsen@utah.gov); [stacey.brayboy@governor.virginia.gov](mailto:stacey.brayboy@governor.virginia.gov); [Jason.gibbs@vermont.gov](mailto:Jason.gibbs@vermont.gov); [Morgan.Wilson@gov.wa.gov](mailto:Morgan.Wilson@gov.wa.gov); [casey.katims@gov.wa.gov](mailto:casey.katims@gov.wa.gov); [barb.worcester@wisconsin.gov](mailto:barb.worcester@wisconsin.gov); [rebecca.d.blaine@wv.gov](mailto:rebecca.d.blaine@wv.gov); [rob.creager@wyo.gov](mailto:rob.creager@wyo.gov); [renny.mackay@wyo.gov](mailto:renny.mackay@wyo.gov); [Scott.Harris@adph.state.al.us](mailto:Scott.Harris@adph.state.al.us); [anne.zink@alaska.gov](mailto:anne.zink@alaska.gov); [tuinua@doh.as](mailto:tuinua@doh.as); [cara.christ@azdhs.gov](mailto:cara.christ@azdhs.gov); [nathaniel.smith@arkansas.gov](mailto:nathaniel.smith@arkansas.gov); [susan.fanelli@cdph.ca.gov](mailto:susan.fanelli@cdph.ca.gov); [charity.dean@cdph.ca.gov](mailto:charity.dean@cdph.ca.gov); [jill.hunsakerryan@state.co.us](mailto:jill.hunsakerryan@state.co.us); [Renee.Coleman-Mitchell@ct.gov](mailto:Renee.Coleman-Mitchell@ct.gov); [karyl.rattay@state.de.us](mailto:karyl.rattay@state.de.us); [laquandra.nesbitt@dc.gov](mailto:laquandra.nesbitt@dc.gov); [scott.rivkees@flhealth.gov](mailto:scott.rivkees@flhealth.gov); 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[Thomas.Dobbs@msdh.ms.gov](mailto:Thomas.Dobbs@msdh.ms.gov); [Randall.williams@health.mo.gov](mailto:Randall.williams@health.mo.gov); [sheilahogan@mt.gov](mailto:sheilahogan@mt.gov); [Gholzman@mt.gov](mailto:Gholzman@mt.gov); [dannette.smith@nebraska.gov](mailto:dannette.smith@nebraska.gov); [Gary.Anthone@nebraska.gov](mailto:Gary.Anthone@nebraska.gov); [l.sherych@health.nv.gov](mailto:l.sherych@health.nv.gov); [lisa.morris@dhhs.nh.gov](mailto:lisa.morris@dhhs.nh.gov); [Judith.Persichilli@doh.nj.gov](mailto:Judith.Persichilli@doh.nj.gov); [kathy.kunkel@state.nm.us](mailto:kathy.kunkel@state.nm.us); [Abinash.Achrekar@state.nm.us](mailto:Abinash.Achrekar@state.nm.us); [howard.zucker@health.ny.gov](mailto:howard.zucker@health.ny.gov); [mark.benton@dhhs.nc.gov](mailto:mark.benton@dhhs.nc.gov); [Betsey.Tilson@dhhs.nc.gov](mailto:Betsey.Tilson@dhhs.nc.gov); [mylynntufte@nd.gov](mailto:mylynntufte@nd.gov); [esther.muna@dph.gov.mp](mailto:esther.muna@dph.gov.mp); [amy.acton@odh.ohio.gov](mailto:amy.acton@odh.ohio.gov); 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[jmwiesman@doh.wa.gov](mailto:jmwiesman@doh.wa.gov); [cathy.c.slemp@wv.gov](mailto:cathy.c.slemp@wv.gov); [jeanne.ayers@dhs.wisconsin.gov](mailto:jeanne.ayers@dhs.wisconsin.gov); [alexia.harrist1@wyo.gov](mailto:alexia.harrist1@wyo.gov); Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]

**Subject:** FDA Authorizes Blood Purification Device to Treat COVID-19

Good Morning

The U.S. FDA's Intergovernmental Affairs (IGA) team would like to bring to your attention two announcements issued today by the FDA.

The first announcement is FDA Authorizes Blood Purification Device to Treat COVID-19. FDA issued an emergency use authorization for a blood purification system to treat patients 18 years of age or older with confirmed Coronavirus Disease 2019 (COVID-19) admitted to the intensive care unit (ICU) with confirmed or imminent respiratory failure. This announcement can be found in its entirety at this link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-blood-purification-device-treat-covid-19>

The second announcement is FDA Issues Second Emergency Use Authorization to Decontaminate N95 Respirators. FDA also issued the second emergency use authorization to decontaminate compatible N95 or N95-equivalent respirators for reuse by health care workers in hospital settings. This EUA will support decontamination of approximately 750,000 N95 respirators per day in the U.S. This announcement can be found in its entirety at this link: <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-second-emergency-use-authorization-decontaminate-n95>

We hope this information is helpful to you.

For general FDA-related inquiries, please feel free to contact FDA's IGA staff at [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov).

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**From:** Herring, Kenneth (Lee) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=24DA18002BF64AE788C452B94F4BB12A-KENNETH.HER]  
**Sent:** 7/2/2020 4:15:00 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue JULY 2 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.07.02\_FINAL ToGoOut.docx

Hi –

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Lee

**K. Lee Herring**  
Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Cell: (b)(6)  
lee.herring@fda.hhs.gov

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 7/2/2020 7:36:37 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** FW: Coronavirus (COVID-19) Update: Daily Roundup July 2, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration (FDA) today continued to take action in the ongoing response to the COVID-19 pandemic:

- The U.S. Food and Drug Administration (FDA) issued an updated FDA COVID-19 Response At-A-Glance Summary that provides a quick look at facts, figures, and highlights of the agency's response efforts.
- As part of continued action to protect the American public, the FDA is warning consumers and health care professionals about hand sanitizer products that contain methanol (a.k.a. wood alcohol), a substance often used to create fuel and antifreeze. Methanol is not an acceptable active ingredient for hand sanitizer products and can be toxic when absorbed through the skin as well as life-threatening when ingested. The agency has seen an increase in hand sanitizer products that are labeled as containing ethanol (also known as ethyl alcohol) but that have tested positive for methanol contamination. State officials have also reported recent adverse events from adults and children ingesting hand sanitizer products contaminated with methanol, including blindness, hospitalizations and death.
- Testing updates:
  - To date, the FDA has currently authorized 162 tests under EUAs; these include 136 molecular tests, 25 antibody tests, and 1 antigen test.

#### **Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**To:** OP Policy Review Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=880566a7249e4495973f6957997d7031-OP Policy R]  
**Subject:** FW: DUE JULY 13: Draft Response to NY Assemblyman Montesano's inquiry on approval process for COVID-19 vaccines: Correspondence Control # 2020-2742 (C20-321)  
**Attachments:** NY Assemblyman Vaccine Inquiry Response.docx

Good morning OP,

FDA received the attached correspondence from NY Assemblyman, Michael A. Montesano, asking President Trump to ensure the process for COVID-19 vaccines is not rushed in order to get the product to market faster. The incoming letter is embedded in the attached draft response. Please review the draft response and clear by July 13.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** aimssystem@fda.hhs.gov <aimssystem@fda.hhs.gov>  
**Sent:** Thursday, June 18, 2020 3:20 PM  
**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>  
**Subject:** Referral from FDA/OC/OES/ on Correspondence Control # 2020-2742

Note: Do NOT reply directly to this E-mail

A referral has been sent to your office by FDA/OC/OES/ on Correspondence Control # 2020-2742 requesting your assistance. A summary of the referral appears below. If you have any questions, please contact CARMILA J. LESANE of FDA/OC/OES/.

**Action:** Direct Reply  
**Due Date:** Wednesday, July 1, 2020  
**Synopsis:** Department D/R- Assemblyman Michael A. Montesano with the 15th Assembly District asking President Trump can he ensure the process for COVID-19 vaccines is not rushed in order to get the product to market faster.

Please click the URL below to access the referral:

[http://aims.fda.gov/\\_cktoken/ct\\_token.mainPage?p\\_token=xv87egjri03rfbn64t300000zwbtdn00001lkgsteo78283428xm\\_8zn4zai20xkj](http://aims.fda.gov/_cktoken/ct_token.mainPage?p_token=xv87egjri03rfbn64t300000zwbtdn00001lkgsteo78283428xm_8zn4zai20xkj)

You can view the original correspondence by clicking the button 'View Orig Corr' (if available). After reviewing all the information provided, please acknowledge receipt of the referral by clicking either the ACCEPT button or the DECLINE button.

If you ACCEPT the referral, a new COMPLETE button is immediately displayed. You can either:

Click the COMPLETE button to complete the referral now

OR

You MUST retain this e-mail with the above URL until you have completed the referral request. Click the above URL again and click the COMPLETE button.

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**From:** Jackson, Valerie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CBEAC5D29BA247128B43177B06D5D847-VJACKSON]  
**Sent:** 7/6/2020 1:30:54 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**Subject:** Documents for 2020-2959  
**Attachments:** ES Note SPS00439030 - Inslee response letter.docx; PR-074892 - Gov. Jay Inslee - Jun 10 20.pdf

**Importance:** High

Hi Erica,

Here are the documents and I will update Governor Inslee's title.

Valerie

---

**From:** Russ, Wanda <Wanda.Russ@fda.hhs.gov>  
**Sent:** Sunday, July 5, 2020 8:25 AM  
**To:** Jackson, Valerie <Valerie.Jackson@fda.hhs.gov>  
**Subject:** Department R/C  
**Importance:** High

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**Sent:** 7/6/2020 3:19:52 PM  
**Subject:** FW: Documents for 2020-2959  
**Attachments:** ES Note SPS00439030 - Inslee response letter.docx; PR-074892 - Gov. Jay Inslee - Jun 10 20.pdf

**Importance:** High

Good afternoon,

HHS is asking for review and clearance of the attached response letter to Washington State Gov. Jay Inslee. Gov. Inslee's incoming letter, also attached, encourages the federal government to increase domestic production of personal protective equipment using the Defense Production Act, assess supply chain gaps, provide guidance for workers, and replenish the Strategic National Stockpile. Please review and clear by **COB Tuesday, July 7**.



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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 7/6/2020 3:45:56 PM  
**To:** Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** FW: Referral from FDA/OC/OES: Gov. Jay Inslee (WA) re: regarding increase domestic  
**Attachments:** ES Note SPS00439030 - Inslee response letter.docx; PR-074892 - Gov. Jay Inslee - Jun 10 20.pdf

**Importance:** High

I forgot to include you in this email. It's a new request.

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**From:** White, Erica  
**Sent:** Monday, July 6, 2020 3:24 PM  
**To:** Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; CDRH ExecSec <execsec@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Referral from FDA/OC/OES: Gov. Jay Inslee (WA) re: regarding increase domestic  
**Importance:** High

Good afternoon,

HHS is asking for review and clearance of the attached response letter to Washington State Gov. Jay Inslee. Gov. Inslee's incoming letter, also attached, encourages the federal government to increase domestic production of personal protective equipment using the Defense Production Act, assess supply chain gaps, provide guidance for workers, and replenish the Strategic National Stockpile. Please review and clear the draft response by **COB Tuesday, July 7**.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov



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**From:** IGA [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5D83EA35D9E24B7894ADA449EF16A9C3-IGA]  
**Sent:** 7/6/2020 9:12:48 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinua@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; andrea.l.fisher@wv.gov; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynnstufe@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6) emails.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Pierce@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; Stephanie.Smiley@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hkllaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Brown, Akeisha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=802c3f43976c4eae88f559c26cb51be5-Akeisha.Bro]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup July 6, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration today announced the following actions taken in its ongoing response effort to the COVID-19 pandemic:

- The FDA added content to the question-and-answer appendix in its guidance titled “Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency.” The updated guidance clarifies two previously suggested methods for obtaining informed consent from a hospitalized patient in isolation. In addition, the guidance includes a new question-and-answer regarding how to obtain informed consent from a prospective trial participant in certain circumstances where the enrollment timeframe is limited and the patient can receive a copy of an informed consent document electronically but cannot sign it electronically or print it out for signature. The guidance also clarifies recommendations on documenting details when using video conferencing for trial visits.

- The FDA issued an emergency use authorization (EUA) for the third diagnostic test for detection and differentiation of the viruses that cause flu and COVID-19 in individuals suspected of COVID-19 by their healthcare provider to the Centers for Disease Control and Prevention (CDC). The FDA has previously issued EUAs to BioFire Diagnostics, LLC and QIAGEN GmbH for their tests, which include many other respiratory organisms in addition to the viruses that cause flu and COVID-19. These combination tests work by testing a single sample from a patient for multiple respiratory diseases. Tests based on taking just one sample from a patient may help alleviate the need for multiple sample collections, which means less discomfort for the patient with faster and more comprehensive results. The FDA encourages additional developers to work with the FDA on combination tests that may be useful in preserving critical testing resources during the upcoming flu season.

- On July 2, 2020, the U.S. Food and Drug Administration (FDA) issued the second Emergency Use Authorization (EUA) for a COVID-19 antigen test. An antigen test is a diagnostic test that quickly detects fragments of proteins found on or within the virus by testing samples collected from the patient’s nasal cavity using swabs. The EUA was issued to Becton, Dickinson and Company (BD) for the BD Veritor System For Rapid Detection of SARS-CoV-2. Antigen tests can provide results in minutes, be produced at a lower cost than molecular tests, and potentially scale to test millions of Americans per day once multiple manufacturers enter the market. However, antigen tests may not detect all active infections, as they do not work the same way as a PCR test. The FDA will continue to support the development, review, and monitoring of tests to help ensure accuracy while balancing the urgent need for these critical diagnostics.

- Testing updates:

- To date, the FDA has currently authorized 164 tests under EUAs; these include 137 molecular tests, 25 antibody tests, and 2 antigen tests.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 7/8/2020 8:03:06 AM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2c4cd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** Re: (b)(6)

Sure.

Thank you,

**Erica M. White, J.D.**  
**Intergovernmental Affairs (IGA)**  
**Office of the Commissioner/OPLIA**  
**U.S. Food and Drug Administration**  
**Office: (301)796-8309**  
Erica.White@fda.hhs.gov

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Date:** July 7, 2020 at 2:31:05 PM EDT  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>  
**Subject:** (b)(6)

Could you listen to this hearing and see if anything is said that suggests we should reach out to the states testifying? Thanks.

**COMMITTEE:** House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response and Recovery

**SUBJECT:** National Response to Worsening COVID-19 Pandemic

**DATE/TIME:** Wednesday, July 8, 2020 at 12:00pm; Hearing will be held remotely

**WITNESSES:**

1. Jay Robert "J. B." Pritzker, Governor, Illinois
2. Jason Shelton, Mayor, City of Tupelo, Mississippi
3. Umair A. Shah, M.D., M.P.H., Executive Director and Local Health Authority of Harris County Public Health, Texas
4. Brian Hastings, Col (ret) USAF, Director, Alabama Emergency Management Agency

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**From:** Groves, Garrick (HHS/ASL) <Garrick.Groves@hhs.gov>  
**Sent:** Tuesday, July 07, 2020 8:59 AM  
**To:** Groves, Garrick (OS) <Garrick.Groves@hhs.gov>  
**Subject:** ASL Daily Memo for July 7, 2020

**Department of Health and Human Services**  
**Office of the Assistant Secretary for Legislation**

**ASL Daily Memo for July 7, 2020**  
(\* denotes new or updated item)

**The Senate** is not in session.

The House is not in session.

## SENATE

None.

## HOUSE

**COMMITTEE:** House Committee on Appropriations, Subcommittee on Labor, Health and Human Services, Education, and Related Agencies

**SUBJECT:** Subcommittee Markup

**\*DATE/TIME:** Tuesday, July 7, 2020 at 5:00pm; 2123 Rayburn House Office Building; Note: Livestream at <https://www.youtube.com/watch?v=06bg4glO NU&feature=youtu.be>

**COMMITTEE:** House Committee on Energy and Commerce

**SUBJECT:** Tribal Community Health-Environmental-Accessibility Needs

**DATE/TIME:** Wednesday, July 8, 2020 at 12:00pm; via Cisco Webex

**WITNESSES:** TBA

**COMMITTEE:** House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response and Recovery

**SUBJECT:** National Response to Worsening COVID-19 Pandemic

**DATE/TIME:** Wednesday, July 8, 2020 at 12:00pm; Hearing will be held remotely

**WITNESSES:**

5. Jay Robert "J. B." Pritzker, Governor, Illinois
6. Jason Shelton, Mayor, City of Tupelo, Mississippi
7. Umair A. Shah, M.D., M.P.H., Executive Director and Local Health Authority of Harris County Public Health, Texas
8. Brian Hastings, Col (ret) USAF, Director, Alabama Emergency Management Agency

**COMMITTEE:** House Committee on Financial Services, Artificial Intelligence Task Force Subcommittee

**SUBJECT:** Exposure Notification and Contact Tracing

**DATE/TIME:** Wednesday, July 8, 2020 at 12:00pm; via Cisco Webex

**WITNESSES:** TBA

**COMMITTEE:** House Committee on Homeland Security, Subcommittee on Emergency Preparedness, Response and Recovery

**SUBJECT:** Unequal Impacts of COVID-19

**DATE/TIME:** Friday, July 10, 2020 at 12:00pm; Hearing will be held remotely

**WITNESSES:**

1. Leana Wen, Visiting Professor of Health Policy and Management in George Washington University Milken Institute School of Public Health
1. Georges C. Benjamin, Executive Director of the American Public Health Association
1. Chauncia Willis, Co-Founder and CEO of the Institute for Diversity and Inclusion in Emergency Management

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**Sent:** 7/8/2020 11:27:37 PM  
**To:** White, Erica (Erica.White@fda.hhs.gov) [/o=FDA/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=Erica.White]  
**BCC:** jblumenstock@astho.org; cmullen@astho.org; acasalotti@naccho.org; haley.nicholson@ncsl.org; margaret.wile@ncsl.org; htewarson@nga.org; swilkniss@nga.org; Scott.Harris@adph.state.al.us; anne.zink@alaska.gov; tuinoa@doh.as; cara.christ@azdhs.gov; nathaniel.smith@arkansas.gov; susan.fanelli@cdph.ca.gov; charity.dean@cdph.ca.gov; jill.hunsakerryan@state.co.us; Renee.Coleman-Mitchell@ct.gov; karyl.rattay@state.de.us; laquandra.nesbitt@dc.gov; scott.rivkees@flhealth.gov; kathleen.toomey@dph.ga.gov; msamo@fsmhealth.fm; Linda.denorcey@dphss.guam.gov; bruce.s.anderson@doh.hawaii.gov; elke.shaw-tulloch@dhw.idaho.gov; Ngozi.Ezike@illinois.gov; kbox@isdh.in.gov; gerd.clabaugh@idph.iowa.gov; lee.norman@ks.gov; alexander.billiou@la.gov; nirav.shah@Maine.Gov; robert.neall@maryland.gov; fran.phillips@maryland.gov; monica.bharel@state.ma.us; KhaldunJ@michigan.gov; jan.malcolm@state.mn.us; Thomas.Dobbs@msdh.ms.gov; Randall.williams@health.mo.gov; sheilahogan@mt.gov; Gholzman@mt.gov; dannette.smith@nebraska.gov; Gary.Anthone@nebraska.gov; l.sherych@health.nv.gov; adearinger@kentucky.gov; lisa.morris@dhhs.nh.gov; Judith.Persichilli@doh.nj.gov; kathy.kunkel@state.nm.us; Abinash.Achrekar@state.nm.us; howard.zucker@health.ny.gov; mark.benton@dhhs.nc.gov; Betsey.Tilson@dhhs.nc.gov; mylynntufte@nd.gov; esther.muna@dph.gov.mp; amy.acton@odh.ohio.gov; Commissioner@health.ok.gov; lillian.shirley@state.or.us; ralevine@pa.gov; DrRafael.Rodriguez@salud.pr.gov; Catherine.delacruz@salud.pr.gov; (b)(6)@gmail.com; emais.roberts@palahealth.org; Nicole.alexanderscott@health.ri.gov; rick.toomey@dhec.sc.gov; kim.malsam-rysdon@state.sd.us; Lisa.Piercey@tn.gov; John.Hellerstedt@dshs.texas.gov; justa.encarnacion@doh.vi.gov; joeminer@utah.gov; mark.levine@vermont.gov; norm.oliver@vdh.virginia.gov; jmwiesman@doh.wa.gov; cathy.c.slemp@wv.gov; jeanne.ayers@dhs.wisconsin.gov; alexia.harrist1@wyo.gov; gconger@az.gov; Katie.wheelermathews@wdc.ca.gov; eve.otoole@hklaw.com; jason@turnberrysolutionsllc.com; eve.lieberman@state.co.us; dan.desimone@ct.gov; sheila.grant@state.de.us; Katherine.Russo@eog.myflorida.com; Ben@potomacsouthllc.com; madeleine.bordallo@guam.gov; kymberly.m.sparlin@hawaii.gov; stephanie.groen@iowa.gov; bobbi-jo.meuleman@gov.idaho.gov; Andrew.mitzel@gov.idaho.gov; Pat.Collier@illinois.gov; debbie@indianagr.com; Timothy.Graham@ks.gov; adam@vikingnav.com; Alicia.Williams@la.gov; kevin.mccolaugh@state.ma.us; tiffany.waddell@maryland.gov; ariel.judah@maryland.gov; bethany.beausang@maine.gov; Linda.Pistner@maine.gov; Derek.Langhauser@maine.gov; Michael.Perry@maine.gov; Jeremy.Kennedy@maine.gov; Brousseauj@michigan.gov; SherryD2@michigan.gov; ReadingerP@michigan.gov; sasha.bergman@state.mn.us; David.Bilger@governor.mo.gov; annehall.brashier@govreeves.ms.gov; aschafer@mt.gov; lorea.stallard@nc.gov; Jordan.Whichard@nc.gov; jim.mccleskey@nc.gov; jabeehler@nd.gov; Lauren.kintner@nebraska.gov; David.Bettencourt@nh.gov; Alexandria.Hermann@nj.gov; courtney.kerster@state.nm.us; khudak@cassidy.com; Aebiner@cassidy.com; Alexander.Cochran@exec.ny.gov; Nikki.Guilford@governor.ohio.gov; Karla.Carpenter@Governor.Ohio.gov; Samantha.Davidson@sos.ok.gov; Annie.MCCOLAUGH@oregon.gov; msnead@pa.gov; jstoripan@prfaa.pr.gov; david.ortiz@governor.ri.gov; JMarsh@governor.sc.gov; Kennedy.Noem@state.sd.us; Chris.Walker@tn.gov; wes.hambrick@gov.texas.gov; teri.helenese@go.vi.gov; Gordonlarsen@utah.gov; stacey.brayboy@governor.virginia.gov; Jason.gibbs@vermont.gov; Morgan.Wilson@gov.wa.gov; casey.katims@gov.wa.gov; barb.worcester@wisconsin.gov; rebecca.d.blaine@wv.gov; rob.creager@wyo.gov; renny.mackay@wyo.gov; Meister, Karen G [Karen.Meister@fda.hhs.gov]  
**Subject:** FDA Authorizes First Diagnostic Test Using At-Home Collection of Saliva Specimens

Good afternoon,

The FDA Intergovernmental Affairs team would like to bring to your attention that today, the U.S. Food and Drug Administration authorized the first diagnostic test with the option of using home-collected saliva samples for COVID-19 testing. Specifically, the FDA issued an emergency use authorization (EUA) to Rutgers Clinical Genomics Laboratory for their COVID-19 laboratory developed test (LDT), which had been previously added to the high complexity molecular-based LDT "umbrella" EUA, to permit testing of samples self-collected by patients at home using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. This announcement builds on last month's EUA for the first diagnostic test with a home-collection option, which uses a sample collected from the patient's nose with a nasal swab and saline.

"Authorizing additional diagnostic tests with the option of at-home sample collection will continue to increase patient access to testing for COVID-19. This provides an additional option for the easy, safe and convenient

collection of samples required for testing without traveling to a doctor's office, hospital or testing site," said FDA Commissioner Stephen M. Hahn, M.D. "We will continue to work around the clock to support the development of accurate and reliable tests, as we have done throughout this pandemic. The FDA has authorized more than 80 COVID-19 tests and adding more options for at-home sample collection is an important advancement in diagnostic testing during this public health emergency."

Today's EUA for Rutgers Clinical Genomics Laboratory's molecular test permits testing of a saliva sample collected from the patient using a designated self-collection kit. Once patients collect their saliva sample, they return it to the Rutgers Clinical Genomics Laboratory in a sealed package for testing.

The Rutgers Clinical Genomics Laboratory test is currently the only authorized COVID-19 diagnostic test that uses saliva samples to test for SARS-CoV-2, the strain of coronavirus that causes COVID-19. The test remains prescription only.

Today's authorization is limited to testing performed at the Rutgers Clinical Genomics Laboratory using their molecular LDT COVID-19 authorized test for saliva specimens collected using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device. It is important to note that this is not a general authorization for at-home collection of patient samples using other collection methods, saliva collection devices, or tests, or for tests fully conducted at home.

**Additional Resources:**

- [Novel Coronavirus](#)
- [Emergency Use Authorization: Coronavirus](#)

If you have any questions please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)



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**Sent:** 7/9/2020 4:05:46 PM  
**To:** OC OCC General Requests Mailbox [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c88a206ddbc459399e17140a29f59a5-OCOCCGenera]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Referral from FDA/OC/OES: Gov. Jay Inslee (WA) re: regarding increase domestic  
**Attachments:** ES Note SPS00439030 - Inslee response letter.docx; PR-074892 - Gov. Jay Inslee - Jun 10 20.pdf

**Importance:** High

Good afternoon OP,

HHS is asking for review and clearance of the attached response letter to Washington State Gov. Jay Inslee. Gov. Inslee's incoming letter, also attached, encourages the federal government to increase domestic production of personal protective equipment using the Defense Production Act, assess supply chain gaps, provide guidance for workers, and replenish the Strategic National Stockpile. Please review and clear the draft response at your earliest convenience. CDRH did not have any comments regarding the draft.

Thank you,

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-3309  
Erica.White@fda.hhs.gov





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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 7/10/2020 2:13:03 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Okay.

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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:12 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Toally agree but ask Gary to keep us informed in real time so we can keep Tiffany (gov office rep) informed.

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:11 PM  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** FW: Maryland Gov's Office shipment inquiry

Let me know how you would like to handle. I am fine with ORA handling it based on the SLA. I know Nick is big on the SLA's and following them, so let me what you want to do.

Erica

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**From:** Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 2:07 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Hi Erica,

Both Mike Verdi and I have talked with Nick Scire and informed him that I should be handling this operational state inquiry and not the ORA Executive Secretariat Staff (ESS) or IGA Staff per the FDA Regulatory Procedures Manual, Chapter 10-13 and the 2014 Service Level Agreement between ORA/OPPLA. Understanding that this is a time-sensitive inquiry and you are already working on it, are you available for a quick chat to discuss how to best handle it? Please advise.

Thanks,  
Gary

**Gary Norris**, MS, MPA, ASQ CMQ/OE, MT(ASCP)SBB  
Federal-State Health Communications and Relations Program Manager  
Division of Communications  
Office of Communications and Project Management

**U.S. Food and Drug Administration**  
Office of Regulatory Affairs  
5630 Fishers Lane, RM 1089  
Rockville, Maryland

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Email: Gary.Norris@fda.hhs.gov



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**From:** Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 12:36 PM  
**To:** Windt, David <David.Windt@fda.hhs.gov>; Aldridge, Megan <Megan.Aldridge@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; 2019-nCoV FDA IMG JIC ORA <2019-nCoV-FDA-IMG-JIC-ORA@fda.hhs.gov>; Eng, Rebecca <Rebecca.Eng@fda.hhs.gov>; Hileman, Christine <Christine.Hileman@fda.hhs.gov>; Kwisnek, Stephanie <Stephanie.Kwisnek@fda.hhs.gov>; Ramsey, Kathy <Kathy.Ramsey@fda.hhs.gov>; Verdi, Michael J <MichaelJ.Verdi@fda.hhs.gov>; Willis, Trudie <Trudie.Willis@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Good afternoon all,

For awareness, this inquiry is being followed-up through our traditional process at ORA Exec Sec.

Thanks,

Nick Scire  
2019 Novel Coronavirus (nCoV) IMG  
ORA Field Activities  
Emergency Operations Center

Cell: (b)(6)

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**From:** Windt, David <David.Windt@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:45 AM  
**To:** Aldridge, Megan <Megan.Aldridge@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; 2019-nCoV FDA IMG JIC ORA <2019-nCoV-FDA-IMG-JIC-ORA@fda.hhs.gov>; Eng, Rebecca <Rebecca.Eng@fda.hhs.gov>; Hileman, Christine <Christine.Hileman@fda.hhs.gov>; Kwisnek, Stephanie <Stephanie.Kwisnek@fda.hhs.gov>; Ramsey, Kathy <Kathy.Ramsey@fda.hhs.gov>; Verdi, Michael J <MichaelJ.Verdi@fda.hhs.gov>; Willis, Trudie <Trudie.Willis@fda.hhs.gov>  
**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Adding ORA JIC and Exec Sec.

**David Windt**  
*Lead Health Communication Specialist*  
*COVID-19 Outbreak Response, FDA IMG – JIC / ORA Comms*

**U.S. Food and Drug Administration**

T: 240-402-9993 M (b)(6)

[David.windt@fda.hhs.gov](mailto:David.windt@fda.hhs.gov)

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**From:** Aldridge, Megan <[Megan.Aldridge@fda.hhs.gov](mailto:Megan.Aldridge@fda.hhs.gov)>

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**Subject:** RE: Maryland Gov's Office shipment inquiry

Erica,

Thank you for the notification. Operations will look into the issue.

Nick- Can you reach out to ORA Imports to look into these entries for the Governor's Office? Below are the entry numbers.

Thank you,

*Megan R. Aldridge, MPH*

Operations Sections Chief

2019 Novel Coronavirus (nCoV) Incident Management Group

Office of Emergency Management

U.S. Food and Drug Administration

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24-Hour Telephone: 1-866-300-4374

email: [megan.aldridge@fda.hhs.gov](mailto:megan.aldridge@fda.hhs.gov)

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 think you have received this e-mail message in error, please e-mail the sender immediately at [megan.aldridge@fda.hhs.gov](mailto:megan.aldridge@fda.hhs.gov)

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**Subject:** Maryland Gov's Office shipment inquiry

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Can you please check on the status of this shipment and the FDA review to see if there is any information that can be provided to quickly move along the FDA review and also get a sense of when this shipment is anticipated to be released? The Customs Entry Numbers for the shipments are # EAE-0508378-5; EAE-0508482-5; EAE-0508481-7.

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2040 Enterprise Boulevard, Suite 140

West Sacramento, CA 95691

2) Ohio Department of Health  
P0006421, 5835 West Green Pointe Drive  
RSS Warehouse, Suite C & D  
Groveport, OH 43125

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:21 AM  
**To:** Tiffany Waddell -GOV- <tiffany.waddell@maryland.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Re: Follow-Up to Wednesday's Call

We will look into it and get back to you. Karen

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**Date:** July 10, 2020 at 11:12:06 AM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
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Groveport, OH 43125

Any further information you can share, or assistance you can provide with this issue would be greatly appreciated.

Best Regards,  
Tiffany

--

-----

**Tiffany Waddell**

Senior Advisor & Director, Federal Relations  
Office of the Governor

444 N. Capitol Street NW Suite 311

Washington, DC 20001

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**Sent:** 7/10/2020 3:17:03 PM  
**To:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** FW: Maryland Gov's Office shipment inquiry

Gary said he would send the response back to us so we can send it.

Erica

---

**From:** Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 3:15 PM  
**To:** Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Aldridge, Megan <Megan.Aldridge@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>; 2019-nCoV FDA IMG JIC ORA <2019-nCoV-FDA-IMG-JIC-ORA@fda.hhs.gov>; Eng, Rebecca <Rebecca.Eng@fda.hhs.gov>; Hileman, Christine <Christine.Hileman@fda.hhs.gov>; Kwisnek, Stephanie <Stephanie.Kwisnek@fda.hhs.gov>; Ramsey, Kathy <Kathy.Ramsey@fda.hhs.gov>; Verdi, Michael J <MichaelJ.Verdi@fda.hhs.gov>; Willis, Trudie <Trudie.Willis@fda.hhs.gov>  
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Please let me know if you have any questions or comments.

Thanks,

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**Gary Norris, MS, MPA, ASQ CMQ/OE, MT(ASCP)SBB**  
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Division of Communications  
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**U.S. Food and Drug Administration**

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**Subject:** RE: Maryland Gov's Office shipment inquiry

Good afternoon all,

For awareness, this inquiry is being followed-up through our traditional process at ORA Exec Sec.

Thanks,

Nick Scire

2019 Novel Coronavirus (nCoV) IMG

ORA Field Activities

Emergency Operations Center

Cell 1- 339-293-7849

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**U.S. Food and Drug Administration**

T: 240-402-9993 M: 240-743-1766

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Operations Sections Chief  
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U.S. Food and Drug Administration  
Mobile: (b)(6)  
24-Hour Telephone: 1-866-300-4374  
email: megan.aldridge@fda.hhs.gov

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**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**Sent:** Friday, July 10, 2020 11:21 AM  
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**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Re: Follow-Up to Wednesday's Call

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**From:** Tiffany Waddell -GOV- <tiffany.waddell@maryland.gov>  
**Date:** July 10, 2020 at 11:12:06 AM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Follow-Up to Wednesday's Call

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Any further information you can share, or assistance you can provide with this issue would be greatly appreciated.

Best Regards,  
Tiffany

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**Tiffany Waddell**

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(b)(6) (M)

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**Sent:** 7/10/2020 3:34:12 PM  
**To:** White, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6fa70699685245178c505c69d684872d-Erica.White]  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Sounds good, Erica.  
Thanks,  
Gary

**Gary Norris, MS, MPA, ASQ CMQ/OE, MT(ASCP)SBB**  
Federal-State Health Communications and Relations Program Manager  
Division of Communications  
Office of Communications and Project Management

**U.S. Food and Drug Administration**

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**To:** Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Thank you Gary. Appreciate the team work on this. We will include you when we send the response.

Erica

---

**From:** Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 3:30 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>; Norris, Gary <Gary.Norris@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Hi Erica,

Per our discussion this afternoon, I will take the lead in obtaining the response to this inquiry since it is operational in nature. I normally respond directly back to the requesting officials with the agency's official response; however, as discussed, in this case I will forward the final, cleared response back to IGA so that you can respond back to the state official since Karen has already indicated in her email to the requesting official, Tiffany Waddell, that she will get back with her.

Please let me know if you have any follow-up questions or comments.

Thanks,  
Gary

**Gary Norris**, MS, MPA, ASQ CMQ/OE, MT(ASCP)SBB  
Federal-State Health Communications and Relations Program Manager  
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**From:** Windt, David <[David.Windt@fda.hhs.gov](mailto:David.Windt@fda.hhs.gov)>  
**Sent:** Friday, July 10, 2020 11:45 AM  
**To:** Aldridge, Megan <[Megan.Aldridge@fda.hhs.gov](mailto:Megan.Aldridge@fda.hhs.gov)>; White, Erica <[Erica.White@fda.hhs.gov](mailto:Erica.White@fda.hhs.gov)>; Scire, Nicholas J <[Nicholas.Scire@fda.hhs.gov](mailto:Nicholas.Scire@fda.hhs.gov)>; 2019-nCoV FDA IMG JIC ORA <[2019-nCoV-FDA-IMG-JIC-ORA@fda.hhs.gov](mailto:2019-nCoV-FDA-IMG-JIC-ORA@fda.hhs.gov)>; Eng, Rebecca <[Rebecca.Eng@fda.hhs.gov](mailto:Rebecca.Eng@fda.hhs.gov)>; Hileman, Christine <[Christine.Hileman@fda.hhs.gov](mailto:Christine.Hileman@fda.hhs.gov)>; Kwisnek, Stephanie <[Stephanie.Kwisnek@fda.hhs.gov](mailto:Stephanie.Kwisnek@fda.hhs.gov)>; Ramsey, Kathy <[Kathy.Ramsey@fda.hhs.gov](mailto:Kathy.Ramsey@fda.hhs.gov)>; Verdi, Michael J <[MichaelJ.Verdi@fda.hhs.gov](mailto:MichaelJ.Verdi@fda.hhs.gov)>; Willis, Trudie <[Trudie.Willis@fda.hhs.gov](mailto:Trudie.Willis@fda.hhs.gov)>

**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>  
**Subject:** RE: Maryland Gov's Office shipment inquiry

Adding ORA JIC and Exec Sec.

**David Windt**

*Lead Health Communication Specialist*

*COVID-19 Outbreak Response, FDA IMG – JIC / ORA Comms*

**U.S. Food and Drug Administration**

T: 240-402-9993 M: 240-743-1766

[David.windt@fda.hhs.gov](mailto:David.windt@fda.hhs.gov)

---

**From:** Aldridge, Megan <Megan.Aldridge@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 11:36 AM

**To:** White, Erica <Erica.White@fda.hhs.gov>; Scire, Nicholas J <Nicholas.Scire@fda.hhs.gov>

**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>

**Subject:** RE: Maryland Gov's Office shipment inquiry

Erica,

Thank you for the notification. Operations will look into the issue.

Nick- Can you reach out to ORA Imports to look into these entries for the Governor's Office? Below are the entry numbers.

Thank you,

*Megan R. Aldridge, MPH*

Operations Sections Chief

2019 Novel Coronavirus (nCoV) Incident Management Group

Office of Emergency Management

U.S. Food and Drug Administration

Mobile: (b)(6)

24-Hour Telephone: 1-866-300-4374

email: [megan.aldridge@fda.hhs.gov](mailto:megan.aldridge@fda.hhs.gov)

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**From:** White, Erica <Erica.White@fda.hhs.gov>

**Sent:** Friday, July 10, 2020 11:32 AM

**To:** 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>

**Cc:** 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** Maryland Gov's Office shipment inquiry

Hi IMG,

We received this inquiry from the Maryland Governor's office about a shipment being held at LAX due to an FDA issue.

Can you please check on the status of this shipment and the FDA review to see if there is any information that can be provided to quickly move along the FDA review and also get a sense of when this shipment is anticipated to be released? The Customs Entry Numbers for the shipments are # EAE-0508378-5; EAE-0508482-5; EAE-0508481-7.

The shipment is being sent onto the following locations:

1) California Department of Health  
CADPH Warehouse  
2040 Enterprise Boulevard, Suite 140  
West Sacramento, CA 95691

2) Ohio Department of Health  
P0006421, 5835 West Green Pointe Drive  
RSS Warehouse, Suite C & D  
Groveport, OH 43125

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Sent:** Friday, July 10, 2020 11:21 AM  
**To:** Tiffany Waddell -GOV- <tiffany.waddell@maryland.gov>  
**Cc:** White, Erica <Erica.White@fda.hhs.gov>  
**Subject:** Re: Follow-Up to Wednesday's Call

We will look into it and get back to you. Karen

---

**From:** Tiffany Waddell -GOV- <tiffany.waddell@maryland.gov>  
**Date:** July 10, 2020 at 11:12:06 AM EDT  
**To:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** Follow-Up to Wednesday's Call

Good morning Karen,

I wanted to follow-up from our call on Wednesday evening. UMMS is still unable to get the shipment released from LAX due to an FDA issue. The Customs Entry Number for the shipment is # EAE-0508378-5; EAE-0508482-5; EAE-0508481-7. The shipment is being sent onto the following locations:

1) California Department of Health  
CADPH Warehouse  
2040 Enterprise Boulevard, Suite 140  
West Sacramento, CA 95691

2) Ohio Department of Health  
P0006421, 5835 West Green Pointe Drive  
RSS Warehouse, Suite C & D  
Groveport, OH 43125

Any further information you can share, or assistance you can provide with this issue would be greatly appreciated.

Best Regards,  
Tiffany

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**Tiffany Waddell**  
Senior Advisor & Director, Federal Relations  
Office of the Governor  
444 N. Capitol Street NW Suite 311  
Washington, DC 20001  
tiffany.waddell@maryland.gov  
(202) 624-1432 (O)  
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Website | Facebook | Twitter

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**Tiffany Waddell**  
Senior Advisor & Director, Federal Relations  
Office of the Governor  
444 N. Capitol Street NW Suite 311  
Washington, DC 20001  
tiffany.waddell@maryland.gov  
(202) 624-1432 (O)  
**(b)(6)** (M)  
Website | Facebook | Twitter



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**From:** Herring, Kenneth (Lee) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=24DA18002BF64AE788C452B94F4BB12A-KENNETH.HER]  
**Sent:** 7/13/2020 6:27:42 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue the JULY 13 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.07.13\_FINAL ToGoOut.docx

Hi,

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Lee

**K. Lee Herring**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Cell: (b)(6)  
lee.herring@fda.hhs.gov

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**From:** White, Erica [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6FA70699685245178C505C69D684872D-ERICA.WHITE]  
**Sent:** 7/13/2020 7:32:53 PM  
**To:** IGA [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d83ea35d9e24b7894ada449ef16a9c3-IGA]  
**Subject:** Coronavirus (COVID-19) Update: Daily Roundup July 13, 2020

The FDA Intergovernmental Affairs team would like to bring to your attention the following actions taken by the FDA in its ongoing response effort to the COVID-19 pandemic. Please contact [IGA@fda.hhs.gov](mailto:IGA@fda.hhs.gov) for further information. Thank you!

### **Coronavirus (COVID-19) Update: Daily Roundup**

The U.S. Food and Drug Administration (FDA) today continued to take action in the ongoing response to the COVID-19 pandemic:

- FDA scientists have identified specific areas of the so-called spike proteins on the surface of the COVID-19-causing virus that appear to be key to triggering strong protective antibody responses in rabbits exposed to the virus. The virus uses one part of the spike protein to attach to a cell and another to fuse with the cell membrane, enabling the virus to infect the cell. The scientists studied antibody response to SARS-CoV-2 spike proteins, which could help inform vaccine design by increasing our understanding of the various triggered antibody responses.

As of mid-June, the COVID-19 pandemic has caused more than eight million cases of infection and approximately 450,000 deaths globally, making the development of safe and effective vaccines to prevent this disease a priority. The spike glycoprotein is the key target for protective antibodies against both SARS-CoV-2 (the COVID-19 virus) and the related SARS-CoV-1 virus. Therefore, many vaccine candidates that trigger antibodies — against specific areas on the SARS-CoV-2 spike protein — are being investigated. To help build sufficient scientific knowledge about the quality of antibody responses, the FDA scientists exposed rabbits to the virus and evaluated antibody responses triggered by various SARS-CoV-2 spike antigens that are similar to those being used to develop vaccines to prevent COVID-19.

- Today, FDA released a blueprint for implementing the New Era of Smarter Food Safety, an FDA initiative that represents a new approach to food safety, leveraging technology and other tools to create a more digital, more traceable, and safer food system. The blueprint outlines how FDA plans to usher in this new era. Together with the Food Safety Modernization Act, the blueprint moves the nation's food production closer to achieving an Integrated Food Safety System. Among other factors included in the blueprint implementation are: (1) Tech-enabled traceability to facilitate tracking events and sharing key data across regulatory agencies, industry and other public health partners to avoid duplication of effort and complexity; (2) Smarter tools and methods to prevent and respond to food-borne illness outbreaks through evidence-based improvements in and/or implementation of root-cause analyses, artificial intelligence and machine learning applications for screening imported foods, mutual reliance with FDA's state inspections partners, enhanced outbreak responsiveness, and modernization of product recalls; (3) New business models and retail modernization involving FDA's strategic partners in adapting the regulatory framework to new and innovative business models. FDA will also promote facility and equipment design that support preventive controls for retail food safety management (e.g., the development and use of commercial Smart Kitchen Equipment).

- The FDA has issued emergency use authorizations (EUA) to:
  - electroCore, Inc., for its GammaCore Sapphire Non-invasive Vagus Nerve Stimulator. This stimulator is intended for use at home or in health care settings to treat adult patients with known or suspected COVID-19 who are experiencing worsened asthma-related shortness of breath and reduced airflow, and for whom approved drug therapies are not tolerated or provide insufficient symptom relief as assessed by the patient's healthcare provider. The device improves airflow and provides relief from exacerbated asthma-related shortness of breath in such patients. The device is placed on either side of the patient's neck for two consecutive two-minute stimulations at the onset of respiratory distress or shortness of breath for up to 24 stimulations every 24 hours.

- Circadiance, under the umbrella EUA for ventilators, for its SleepWeaver Prevent CPAP Mask. The product is a CPAP mask that was modified by combining it with an N95.

- Testing updates:

- To date, the FDA has currently authorized 175 tests under EUAs; these include 145 molecular tests, 28 antibody tests, and 2 antigen tests.

**Additional Resources:**

- [FAQs on Testing for SARS-CoV-2](#)
- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\)](#)
- [Coronavirus Disease 2019 \(COVID-19\)](#)

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**From:** Spaulding, Emma [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=33E041DE6759414A8DE9511BEC153A0C-EMMA.SPAULD]  
**Sent:** 7/18/2020 10:36:05 AM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]; OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]  
**CC:** Spaulding, Emma [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=33e041de6759414a8de9511bec153a0c-Emma.Spauld]  
**Subject:** PREPARING TO ISSUE: Coronavirus (COVID-19) Update: FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing ; Press Release  
**Attachments:** Samples Pooling EUA PR 718 1030am.docx

The attached press release will be distributed within the next 30 minutes. Do not share externally until live on FDA.gov.

Thanks,  
Emma

**Emma Spaulding, MPH**  
Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk: 301.796.9423  
Cell: (b)(6)  
emma.spaulding@fda.hhs.gov



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**Sent:** 7/26/2020 12:56:19 PM  
**To:** Jason Osborne [jason@turnberrysolutionsllc.com]  
**CC:** Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]  
**Subject:** RE: FDA Approval Letter

Good morning Jason,

Thank you for the email below regarding the DiaPlexQ Novel Coronavirus (2019-nCoV) Detection Kit. Information about this kit may be found on FDA's Emergency Use Authorization (EUA) website <https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd>. The letter of authorization can be found at this link <https://www.fda.gov/media/138306/download>.

Hopefully this is helpful.

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Jason Osborne <jason@turnberrysolutionsllc.com>  
**Sent:** Tuesday, May 26, 2020 7:38 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>  
**Subject:** FDA Approval Letter

Erica,

Governor Torres received the attached unsigned letter from the South Korean company regarding their EUA approval for their test kit.

The Governor has asked me to verify that it is in fact approved before he purchases any of their kits.

Would you be able to verify it for us?

Thanks Jason Osborne  
CNMI Washington Office Director

Jason Osborne  
202-744-0639

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**Sent:** 7/26/2020 12:56:19 PM  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Good morning,

Below is a follow-up question from Dr. Shah's participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL) a few weeks ago. Any assistance you can provide with answering the question below is greatly appreciated. CBER began answering the question, but your input would be greatly valuable. Please feel free to make any necessary changes to the answer.

**What kind of outreach is used in the Latino Hispanic communities?**

The FDA, Federal research agencies, industry, academia and patient advocacy groups all share the common goal of the development of new technologies that offer treatment options for the prevention or treatment of coronavirus (COVID-19).

As part of this effort the FDA has developed resources in Spanish that provide information about blood and tissue safety, convalescent plasma, vaccine development, surgical masks, diagnostic testing, ventilators, food safety, medical product shortages and more.

This information is available at: <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/preguntas-frecuentes-sobre-la-enfermedad-del-coronavirus-2019-covid-19>

Thank you,

**Erica M. White, J.D.**  
Intergovernmental Affairs (IGA)  
Office of the Commissioner/OPLIA  
U.S. Food and Drug Administration  
Office: (301)796-8309  
Erica.White@fda.hhs.gov



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**From:** Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Sent:** Wednesday, May 20, 2020 4:17 PM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Bartell, Diane <Diane.Bartell@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>; Richards, Paul <Paul.Richards@fda.hhs.gov>; Bell, Maureen <Maureen.Bell@fda.hhs.gov>; Raine, Kristine <Kristine.Raine@fda.hhs.gov>  
**Subject:** RE: Follow Up Questions from Vaccine Webinar

Good afternoon Erica,

Attached please find CBER's responses to the follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL).

Please note in the comments that we recommend reaching out to CDER for the response to the question "What is the timeline for therapies?" And to the Office of Minority Health for the question "What kind of outreach is used in the Latino Hispanic communities?"

Please feel free to contact me if you have any questions.

Best regards,

Amy

Amy Temple

Supervisory Health Communications Specialist (Acting)

Center for Biologics Evaluation and Research  
Office of Communications, Outreach and Development  
U.S. Food and Drug Administration  
Tel: 800-835-4709  
OCOD@fda.hhs.gov



*This informal communication represents my best judgment at this time. It does not constitute an advisory opinion in accordance with 21 CFR 10.85, and does not necessarily represent the formal position of FDA or otherwise obligate the agency to the views expressed.*

---

**From:** Raine, Kristine <Kristine.Raine@fda.hhs.gov>  
**Sent:** Friday, May 1, 2020 9:24 AM  
**To:** Temple, Amy <Amy.Temple@fda.hhs.gov>  
**Cc:** Bell, Maureen <Maureen.Bell@fda.hhs.gov>  
**Subject:** FW: Follow Up Questions from Vaccine Webinar

Hi Amy,

Good Morning. We received another email from IGA asking CBER to assist in providing answers to the below follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures a few weeks ago. Please have CBER keep us in the loop on any responses, and as always if you need CBER Exec Sec's help, please let us know.

Thanks,

Kristine

***Kristine L. Raine, M.S.***  
Consumer Safety Officer  
CBER Consumer Affairs Branch  
Phone: 240-402-8145  
Fax: 301-595-1243  
Email: [Kristine.Raine@fda.hhs.gov](mailto:Kristine.Raine@fda.hhs.gov)

---

**From:** White, Erica <Erica.White@fda.hhs.gov>  
**Sent:** Friday, May 01, 2020 9:09 AM  
**To:** CBER Exec. Sec. <cber\_execsec@fda.hhs.gov>



**Cc:** Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>

**Subject:** FW: Follow Up Questions from Vaccine Webinar

Good morning CBER Exec Sec,

Below are follow-up questions from Dr. Shahs participation in a COVID-19 related webinar hosted by the National Conference of State Legislatures (NCSL) a few weeks ago. Any assistance you can provide with answering the questions below is greatly appreciated. The suggested Center for a response is in parenthesis next to each question.

Thank you for your assistance with this request.

**Erica M. White, J.D.**

Intergovernmental Affairs (IGA)

Office of the Commissioner/OPLIA

U.S. Food and Drug Administration

Office: (301)796-8309

Erica.White@fda.hhs.gov



---

**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>

**Sent:** Thursday, April 30, 2020 4:18 PM

**To:** Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; White, Erica <Erica.White@fda.hhs.gov>

**Subject:** Follow Up Questions from Vaccine Webinar

Good Afternoon Chris and Erica,

I first want to say a huge thanks for all you and your team has helped us with during this time. Below are the questions that came in for Dr. Shah during the webinar but we obviously didn't have time to get to all of them. Would you all be able to take a look and provide any answers that you can? Understandably you may not be able to answer all of them or if some are more directing our members to a resource to read up on we would welcome that. Let me know if you have any questions and thank you again for all you have done for our members and staff!

- It was reported that Oxford University is testing a vaccine that could be available by August of 2020, This would be an incredibly rapid turnaround for a vaccine. Do you feel this might in fact happen? (CBER)
- Even if an effective and safe vaccine is developed, how long would it take to produce and distribute it to large parts of the U.S. population? (CBER)
- What is the actual number of weeks or months on the fast track program? (CBER)
- What is the timeline for therapies? (CBER)
- What kind of outreach is used in the Latino Hispanic communities? (Not sure what they are asking, or whom this would go to?)
- Have there been challenges with participation of Hispanics and African Americans in the clinical trials, as often is the case with the development of other vaccines/medications? (CBER)

- Have there been any supply challenges on the use of existing medicines to treat and/or alleviate symptoms of Covid 19? Can you provide us an brief example of such? (CDER)
- After talking to some physicians on the ER front lines I have the following question: Is there any protocol (or upcoming protocol) for prophylactic use of medications for healthcare professionals dealing with COVID-19 patients? There is apparently a great deal of confusion among them about this. (CDER)

Thank You,

Haley Nicholson  
National Conference of State Legislatures  
Senior Policy Director, Health & Human Services  
State-Federal Affairs  
202-624-8662 (o)



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**From:** Kahn, Jeremy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1B98D36D2C1F4AE795140B68DE7B37F7-JEREMY.KAHN]  
**Sent:** 7/27/2020 11:49:08 AM  
**To:** OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]  
**Subject:** Preparing to Issue: Coronavirus (COVID-19) Update: FDA Reiterates Warning About Dangerous Alcohol-Based Hand Sanitizers Containing Methanol, Takes Additional Action to Address Concerning Products  
**Attachments:** 07192020- FDA Press Release- Sanitizers Methanol UPDATE FINAL wo meta.docx

Good morning-

OMA is preparing to issue the following: Coronavirus (COVID-19) Update: FDA Reiterates Warning About Dangerous Alcohol-Based Hand Sanitizers Containing Methanol, Takes Additional Action to Address Concerning Products

This should be posted to the web in about 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



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**From:** Herring, Kenneth (Lee) [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=24DA18002BF64AE788C452B94F4BB12A-KENNETH.HER]  
**Sent:** 7/27/2020 5:28:44 PM  
**To:** 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]; 2019-nCoV FDA IMG JIC Social [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42666461bd7d4cac84b1ce68ec72d4e7-2019-nCoV F]; OMA-Notifications [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e4fc20a3dda44311971ad6b0e284fc1f-OMA-Notific]  
**CC:** OC OEA OMA-Press [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0300b0a1ab1147298784b94e4a5ed928-OC OEA OMA-]; CDRH COVID19 Leadership Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b44eb33f9db84b499f4e496cf95652eb-CDRH COVID1]  
**Subject:** FYI, preparing to issue the JULY 27 Coronavirus (COVID-19) Update: Daily Roundup  
**Attachments:** 2020.07.27\_FINAL ToGoOut.docx

Hi –

OMA will be issuing the attached Daily Roundup in the next 30 minutes. Thank you!

Best,  
Lee

**K. Lee Herring**

Press Officer

Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
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**Sent:** 7/29/2020 3:08:18 PM  
**To:** michael.queensland@legis.wisconsin.gov  
**CC:** Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; haley.nicholson@ncsl.org  
**Subject:** RE: Request from WI Legislative Staff

Good afternoon Michael,

Thank for your questions regarding the vaccine development process, submitted via NCSL. Below are responses to the questions that fall within FDA's purview. For the questions, that we did not answer, we suggest contacting the Office of Intergovernmental and External Affairs at HHS via [HHSIEA@hhs.gov](mailto:HHSIEA@hhs.gov); or the Center for State, Tribal, Local, and Territorial Support at the CDC via [CSTLTSfeedback@cdc.gov](mailto:CSTLTSfeedback@cdc.gov) for assistance.

**1.The best source of information for a regularly updated list of vaccines for SARS-CoV-2 that are in the development pipeline.**

FDA recognizes the urgent need to develop a vaccine to prevent and therapies to treat COVID-19 and we are working collaboratively with institutions, industry, federal, and domestic and international partners to facilitate the development of these vaccines. At this time there are no FDA-approved drug products to treat COVID-19. FDA has created a special emergency program for possible therapies, the Coronavirus Treatment Acceleration Program (CTAP). As of May 11, 2020, there are 144 active trials of therapeutic agents and another 457 development programs for therapeutic agents in the planning stages. More information can be found at this link: <https://www.fda.gov/media/136832/download>.

**2.Information about use of human challenge trials to accelerate vaccine licensure**

**a.Do you anticipate anyone using this process?**

**b.How would this fit in with three clinical trial phase process that a proposed drug/biologic typically follows? (Would it take the place of a phase III clinical trial?)**

Human challenge studies are a way to expedite the development of a vaccine to prevent COVID-19. Because these studies involve exposing volunteers to the virus, the studies raise a variety of potential scientific, feasibility, and ethical issues. FDA will work with those who are interested in conducting human challenge trials to help them evaluate these issues. A formal determination about any specific human challenge trial proposal would be made by FDA in the context of all the information that is available at that time.

There are various approaches that FDA is using to efficiently advance the development of safe and effective vaccines to prevent COVID-19. The development pathways may differ depending on the vaccine or therapeutic candidate, but development will need to be carefully conceived and rapidly executed, while at the same time ensuring the development of safe and effective vaccines to address the current pandemic. FDA has issued guidance for sponsors related to Investigational New Drug applications for COVID-19 related drugs and biological products and guidance providing FDA's current recommendations on later stage clinical trials intended to establish safety and effectiveness for COVID-19 products. More information is available at <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-new-actions-accelerate-development-novel-prevention-treatment>.

**3. A rough timeline of when a vaccine may be ready.**

**a. Would emergency use authorization be available for certain people, such as healthcare workers, earlier than the general population? If so, when?**

**b. Would the FDA allow a vaccine to be used broadly under emergency use authorization?**

**c.How far along must a vaccine be in the development process before the FDA may grant it emergency use authorization?**

Neither FDA nor the scientific community can predict at this time how quickly data will be generated from vaccine clinical trials, but please be assured that FDA is fully engaged. When clinical data on a particular vaccine or therapy are

available and a company submits an application, FDA will expeditiously evaluate the application to determine whether the data demonstrate the safety and effectiveness of the vaccine.

An Emergency Use Authorization (EUA) can be issued only after several statutory requirements are met. Among these requirements is a determination by the FDA that the known and potential benefits of a product, when used to diagnose, prevent, or treat serious or life-threatening diseases when certain criteria are met, outweigh the known and potential risks of the product. In the case of investigational vaccines being developed for the prevention of COVID-19, this assessment will be made on a case by case basis depending on the characteristics of the product, the preclinical and human clinical study data on the product, and the totality of the available scientific evidence relevant to the product. More information on EUAs, including a list of all current EUAs, is available at <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization>.

FDA is prohibited by regulation and statute from disclosing information about applications pending before the Agency, including a list of clinical trials and application sponsors. However, the National Institute of Health's (NIH) National Institute of Allergy and Infectious Diseases (NIAID) and the Department of Health and Human Services' (HHS) Biomedical Advanced Research and Development Authority (BARDA), as well as sponsors of clinical trials, have made public on their websites certain information on vaccine clinical trials to prevent COVID-19.

**4. Not on the topic of vaccines, but any information about whether FDA approved medicines being used to treat COVID-19 patients are being prescribed for off-label use or whether they are being administered as part of a clinical trial for approval for a new indication would be helpful.**

As noted above, FDA is prohibited by regulation and statute from disclosing information about applications pending before the Agency, including a list of clinical trials and application sponsors. FDA is using every available authority and regulatory flexibility to facilitate the development as quickly as possible of new products to treat patients, while at the same time examining safety and efficacy. We continue to support clinical trials that are testing new products for COVID-19 to gain valuable knowledge about their safety and effectiveness.

FDA is in a public-private partnership with NIH, CDC, ASPR, the EMA, and more than a dozen biopharmaceutical companies to speed COVID-19 vaccine and treatment options, called the Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV).

In conjunction with Operation Warp Speed, the President's initiative to facilitate the development, manufacturing, and distribution of COVID-19 countermeasures, the ACTIV partnership will develop a collaborative framework for prioritizing vaccine and drug candidates, streamlining clinical trials, coordinating regulatory processes and/or leveraging assets among all partners to rapidly respond to the COVID-19 and future pandemics.

As of May 11, FDA is reviewing 19 therapeutic agents in several active clinical trials, such as remdesivir, chloroquine and hydrochloroquine, sarilumab, convalescent plasma, hyperimmune globulin, and others, and is planning to review another 26 agents that are currently in the pre-trial planning phase.

Hopefully this is helpful. If you have additional questions please feel free to contact me.

Thank you,

**Erica M. White, J.D.**

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**From:** Haley Nicholson <Haley.Nicholson@ncsl.org>  
**Sent:** Wednesday, April 29, 2020 9:48 AM  
**To:** White, Erica <Erica.White@fda.hhs.gov>  
**Cc:** Meister, Karen G <Karen.Meister@fda.hhs.gov>  
**Subject:** RE: Request from WI Legislative Staff

Hi Erica,

Please see the staffer's questions and contact information in his signature line below, thank you again.

Good morning,

I am an attorney for the Wisconsin Legislature and I am researching the vaccine development process. I received your contact information from the National Conference of State Legislatures as someone knowledgeable about this issue. While I have some familiarity with the licensure process for biologics, I could use your assistance. Specifically, I would like information about the following:

1. Any federal funding sources for an immunization program for SARS-CoV-2.
2. The best source of information for a regularly updated list of vaccines for SARS-CoV-2 that are in the development pipeline.
3. Information about use of human challenge trials to accelerate vaccine licensure
  - a. Do you anticipate anyone using this process?
  - b. How would this fit in with three clinical trial phase process that a proposed drug/biologic typically follows? (Would it take the place of a phase III clinical trial?)
4. A rough timeline of when a vaccine may be ready.
  - a. Would emergency use authorization be available for certain people, such as healthcare workers, earlier than the general population? If so, when?
  - b. Would the FDA allow a vaccine to be used broadly under emergency use authorization?
  - c. How far along must a vaccine be in the development process before the FDA may grant it emergency use authorization?
5. Once a vaccine is licensed or otherwise made available for use, how will a priority order for who will receive the vaccine first be established?
  - a. By country?
  - b. By profession (e.g. healthcare workers)?
  - c. By region within the United States ("hot spots")?
  - d. Who will decide these issues? The President? FDA and other regulators? WHO?
6. Would the federal government consider ordering people to be vaccinated for SARS-CoV-2? If so, what type of exceptions would you anticipate?
7. Not on the topic of vaccines, but any information about whether FDA approved medicines being used to treat COVID-19 patients are being prescribed for off-label use or whether they are being administered as part of a clinical trial for approval for a new indication would be helpful.

I am very appreciative of any assistance you may be able to provide me. Please feel free to let me know if it would be more convenient to speak by phone.

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Thank you for your help!

Best wishes,  
Mike



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