

---

**From:** Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]  
**Sent:** 4/1/2020 8:18:55 PM  
**To:** Wise, Julie A. EOP/OMB (b) (6); Malliou, Ekaterini (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c57996fad6db44ecba5ab5c1dacf7e0a-HHS-Ekateri]  
**CC:** Hirsch, Quinn N. EOP/OMB (b) (6); Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; OC OPPB OP RPMS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e26c08c0a24020b0200a64ba43a096-OC OPPB OP]  
**Subject:** RE: OMB Clearance: FDA Guidance on Face Masks and Respirators - COVID19

Julie,

For context, FDA, FEMA, and others are getting pinged around the clock about PPE, including KN95 respirators at the border. The (b) (5) are our first priority among things that are at OMB, but this is close second. I know the timing isn't ideal, but we are working flat out here.

Many thanks,  
Lauren

---

**From:** Wise, Julie A. EOP/OMB (b) (6)  
**Date:** April 1, 2020 at 7:42:52 PM EDT  
**To:** Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>  
**Cc:** Hirsch, Quinn N. EOP/OMB (b) (6); Hawkins, Jamar (OS) <jamar.hawkins@hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>  
**Subject:** RE: OMB Clearance: FDA Guidance on Face Masks and Respirators - COVID19

Received – thanks.

We will follow-up with any comments tomorrow morning.

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**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>  
**Sent:** Wednesday, April 1, 2020 7:40 PM  
**To:** Wise, Julie A. EOP/OMB (b) (6) >  
**Cc:** Hirsch, Quinn N. EOP/OMB (b) (6); Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>; Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; FDA Regs Box <OCOPPBOPRPMS@fda.hhs.gov>  
**Subject:** OMB Clearance: FDA Guidance on Face Masks and Respirators - COVID19

Hi Julie,

Attached for OMB review is an FDA guidance on masks and respirators.

It updates the “Enforcement Policy for Face Masks and Respirators” (issued on March 25<sup>th</sup>) and includes three primary changes:

- (1) clarifying that the policy applies to “face shields”,
- (2) providing more regulatory flexibility for Surgical Masks Intended to Provide Liquid Barrier Protection with respect to compliance with registration and listing, quality systems, and UDI during the public health emergency, and
- (3) including a policy for respirators identified in CDC’s crisis strategies guidance, Strategies for optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies.

The redline of the March 25 version is attached to help with the review.

This is a time-sensitive priority, and we would appreciate OMB review as soon possible.

Thank you

\*\*\*\*\*

Ekaterini (Kat) Malliou, DrPH, MPH  
Senior Policy Coordinator  
Immediate Office of the Secretary, U.S. Department of Health and Human Services  
200 Independence Ave SW, Suite 619H, Washington, DC 20201, USA  
Tel: 202-690-6875, Cell: (b) (6) Email: [Ekaterini.Malliou@hhs.gov](mailto:Ekaterini.Malliou@hhs.gov)

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**From:** Pence, Laura (HHS/ASL) [Laura.Pence@hhs.gov]  
**Sent:** 4/1/2020 4:28:45 PM  
**To:** Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Malliou, Ekaterini (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c57996fad6db44ecba5ab5c1dacf7e0a-HHS-Ekateri]  
**CC:** Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; OC OPPB OP RPMS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e26c08c0a24020b0200a64ba43a096-OC OPPB OP]  
**Subject:** RE: HHS Clearance due 5:30pm: FDA Guidance on Face Masks and Respirators - COVID19

(b) (6)

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**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 3:52 PM  
**To:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>  
**Cc:** Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>  
**Subject:** RE: HHS Clearance due 5:30pm: FDA Guidance on Face Masks and Respirators - COVID19

Laura,

Yes, they do fall under section F. We had some concerns about mentioning them specifically, which I can share with you. What is the best number to reach you?

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**From:** Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>  
**Date:** April 1, 2020 at 3:47:40 PM EDT  
**To:** Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>  
**Cc:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>  
**Subject:** RE: HHS Clearance due 5:30pm: FDA Guidance on Face Masks and Respirators - COVID19

Coming into this late and don't want to slow things down. Would like to be a little more explicit about where KN95 fall in this—assuming under “F. Alternatives When FDA-Cleared or NIOSH-Approved N95 Respirators are Not Available”—but assuming there is a reason FDA doesn't want to do that. Would love an answer if possible, but this is cleared.

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**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 3:24 PM  
**To:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Allen-Gifford, Patrice (NIH/OD) [E] <patrice.allen-gifford@nih.gov>; Arellano, Shena (FDA/OC) <Shena.Arellano@fda.hhs.gov>; ASPR Exec Sec (OS/ASPR) (b) (6) >; Barry, Daniel J (HHS/OGC) <daniel.barry@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; cdcregulations@cdc.gov; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; CMS COVID-19 Policy Clearance <COVID-19PolicyClearance@cms.hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Destro, Brenda (HHS/ASPE) <Brenda.Destro@hhs.gov>; Goulding, Michael (HHS/OGC) <Michael.Goulding@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>; Hoffman, Janice (HHS/OGC) <Janice.Hoffman@HHS.GOV>; Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>; Jenny, Brenna (HHS/OGC)

<Brenna.Jenny@hhs.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>; Nevel, Amy (HHS/ASPE) <Amy.Nevel@HHS.GOV>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; OS GCGL, EMAIL (HHS/OS) (b) (6) >; OS OGC-IO ControlDesk (HHS/OS/OGC) (b) (6) >; Parker, Jim (HHS/IOS) <Jim.Parker@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Pollock, Rachel (NIH/OD) [E] <rachel.pollock@nih.gov>; rcc@cdc.gov; Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>; Rowell, Scott (OS/ASA) <Scott.Rowell@hhs.gov>; Schaeffer, Alison (HHS/OS/OGA) <Alison.Schaeffer@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Strom, John (HHS/OGC) <John.Strom@hhs.gov>; Tatem, Anne (HHS/OS/ASL) <Anne.Tatem@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; Uehlecke, Nick (HHS/IOS) <Nicholas.Uehlecke@hhs.gov>; White, Caroline (HHS/OGC) <Caroline.White@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Vitek, Traci (HHS/ASL) <Traci.Vitek@hhs.gov>; Honig, Esther (HHS/ASL) <Esther.Honig@hhs.gov>; Kinney, John (HHS/ASL) <John.Kinney@hhs.gov>

**Cc:** Schiller, Lowell (FDA/OC) <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren (FDA/OC) <Lauren.Roth@fda.hhs.gov>; OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>

**Subject:** RE: HHS Clearance due 5:30pm: FDA Guidance on Face Masks and Respirators - COVID19

Clear without comment for OGC.

---

**From:** Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>

**Sent:** Wednesday, April 1, 2020 3:17 PM

**To:** Agnew, Ann (OS) <Ann.Agnew@hhs.gov>; Allen-Gifford, Patrice L (NIH) <patrice.allen-gifford@nih.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Arellano, Shena <Shena.Arellano@fda.hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Barry, Daniel J (OS) <daniel.barry@hhs.gov>; Bird, Catherine (OS) <Catherine.Bird@hhs.gov>; Bradsher, Kris (OS) <Kris.Bradsher@hhs.gov>; Bratcher-Bowman, Nikki (OS) <nikki.bratcherbowman@hhs.gov>; Campbell, Taylor (OS) <Taylor.Campbell@hhs.gov>; cdcregulations@cdc.gov; Chang, William (OS) <William.Chang@hhs.gov>; CMS COVID-19 Policy Clearance <COVID-19PolicyClearance@cms.hhs.gov>; Dareshori, Zachary (OS) <Zachary.Dareshori@hhs.gov>; Destro, Brenda (OS) <Brenda.Destro@hhs.gov>; Goulding, Michael (OS) <Michael.Goulding@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Hawkins, Jamar (OS) <jamar.hawkins@hhs.gov>; Hecht, Jonah (OS) <Jonah.Hecht@hhs.gov>; Hittle, Taylor (OS) <Taylor.Hittle@hhs.gov>; Hoffman, Janice (OS) <Janice.Hoffman@HHS.GOV>; Horska, Katerina (OS) <Katerina.Horska@hhs.gov>; Jenny, Brenna (OS) <Brenna.Jenny@hhs.gov>; Moughalian, Jen C (OS) <Jen.Moughalian@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Nevel, Amy (OS) <Amy.Nevel@HHS.GOV>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; OS GCGL, EMAIL (HHS/OS) (b) (6) >; OS OGC-IO ControlDesk (HHS/OS/OGC) (b) (6) >; Parker, Jim (OS) <Jim.Parker@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Pollock, Rachel C (NIH) <rachel.pollock@nih.gov>; rcc@cdc.gov; Robinson, Wilma (OS) <Wilma.Robinson@hhs.gov>; Rowell, Scott (OS) <Scott.Rowell@hhs.gov>; Schaeffer, Alison M (OS) <Alison.Schaeffer@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>; Strom, John (OS) <John.Strom@hhs.gov>; Tatem, Anne (OS) <Anne.Tatem@hhs.gov>; Thomas, Gloria D (OS) <Gloria.Thomas@hhs.gov>; Uehlecke, Nicholas (OS) <Nicholas.Uehlecke@hhs.gov>; White, Caroline (OS) <Caroline.White@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Vitek, Traci (OS) <Traci.Vitek@hhs.gov>; Honig, Esther (OS) <Esther.Honig@hhs.gov>; Kinney, John H (OS) <John.Kinney@hhs.gov>

**Cc:** Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>

**Subject:** HHS Clearance due 5:30pm: FDA Guidance on Face Masks and Respirators - COVID19

Attached for your review due 5:30 pm (4/1) is an FDA guidance on masks and respirators.

It updates the “Enforcement Policy for Face Masks and Respirators” (issued on March 25<sup>th</sup>) and includes three primary changes:

(1) clarifying that the policy applies to “face shields”,

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- (3) including a policy for respirators identified in CDC's crisis strategies guidance, Strategies for optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies.

The redline of the March 25 version is attached to help with the review.

Thank you

\*\*\*\*\*

Ekaterini (Kat) Malliou, DrPH, MPH  
Senior Policy Coordinator  
Immediate Office of the Secretary, U.S. Department of Health and Human Services  
200 Independence Ave SW, Suite 619H, Washington, DC 20201, USA  
Tel: 202-690-6875, Cell: (b) (6) Email: [Ekaterini.Malliou@hhs.gov](mailto:Ekaterini.Malliou@hhs.gov)

---

**From:** Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]  
**Sent:** 4/1/2020 9:04:35 PM  
**To:** Krueger, Angela C [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96c8f1f9d6a8481195be2aa3147e0b4f-ACS]  
**Subject:** RE: Guidance

Thanks. After talking to Keagan, I still sent an email to OMB to push them, but I don't expect a response.

---

**From:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 8:57 PM  
**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>  
**Subject:** FW: Guidance

I didn't know what Jeff wanted so reached out. Sounds like we are waiting until the AM.

Angie

---

**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 8:48 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Cc:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>  
**Subject:** RE: Guidance

Thank you

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 8:37 PM  
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Cc:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>  
**Subject:** Re: Guidance

Thanks, I actually just spoke with Lauren about this. I am happy to push, but just pinged them on the (b) (5) that we have to get out tomorrow. I know we are all getting inundated, but I think if I ping them now we likely still won't get a response till am. Happy to do it as always though.

Sent from my iPhone

On Apr 1, 2020, at 8:21 PM, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov> wrote:

Adding Keagan to get her perspective on timing.

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**From:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 8:08 PM  
**To:** Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Subject:** FW: Guidance  
**Importance:** High

Jeff and Bill – how hard does CDRH want to push on the update to the masks/respirators guidance. The updates address a number of issues, including the KN95 issue to some extent. Is tomorrow morning ok or do we want to push for something tonight?

Angie

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**From:** Roth, Lauren <[Lauren.Roth@fda.hhs.gov](mailto:Lauren.Roth@fda.hhs.gov)>  
**Sent:** Wednesday, April 01, 2020 7:46 PM  
**To:** Krueger, Angela C <[Angela.Krueger@fda.hhs.gov](mailto:Angela.Krueger@fda.hhs.gov)>  
**Cc:** Schiller, Lowell <[Lowell.Schiller@fda.hhs.gov](mailto:Lowell.Schiller@fda.hhs.gov)>  
**Subject:** Guidance  
**Importance:** High

Angie – If we posted the guidance tonight (as opposed to tomorrow morning) would it make an important difference from CDRH's perspective? I know we are being deluged with inquiries all over the agency. I'm trying to figure out how hard to push OMB to clear tonight.

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**From:** Lauren.Roth@fda.hhs.gov [Lauren.Roth@fda.hhs.gov]  
**Sent:** 4/1/2020 8:19:03 PM  
**To:** Wise, Julie A. EOP/OMB (b) (6); Malliou, Ekaterini (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c57996fad6db44ecba5ab5c1dacf7e0a-HHS-Ekateri]  
**CC:** Hirsch, Quinn N. EOP/OMB (b) (6); Hawkins, Jamar (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bd7c1a4031647ce89237aef4deb5d89-HHS-jamar.h]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; OC OPPB OP RPMS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e26c08c0a24020b0200a64ba43a096-OC OPPB OP]  
**Subject:** RE: OMB Clearance: FDA Guidance on Face Masks and Respirators - COVID19

Julie,

For context, FDA, FEMA, and others are getting pinged around the clock about PPE, including KN95 respirators at the border. The (b) (5) are our first priority among things that are at OMB, but this is close second. I know the timing isn't ideal, but we are working flat out here.

Many thanks,  
Lauren

---

**From:** Wise, Julie A. (b) (6)  
**Date:** April 1, 2020 at 7:42:52 PM EDT  
**To:** Malliou, Ekaterini (OS) <Ekaterini.Malliou@hhs.gov>  
**Cc:** Hirsch, Quinn N. EOP/OMB <Quinn.N.Hirsch@omb.eop.gov>, Hawkins, Jamar (OS) <jamar.hawkins@hhs.gov>, Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>, Roth, Lauren <Lauren.Roth@fda.hhs.gov>, OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>  
**Subject:** RE: OMB Clearance: FDA Guidance on Face Masks and Respirators - COVID19



---

**From:** Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]  
**Sent:** 3/31/2020 10:35:34 PM  
**To:** Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]  
**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators  
**Attachments:** update - IIE\_Guidance\_COVID-19\_Face\_Masks\_L1 update V7 (OCC Edits 3-31-20).docx

Lowell – Are you up? Can I talk to you about section F?

---

**From:** Beaver, Renee <Renee.Beaver@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 9:07 PM  
**To:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>  
**Cc:** OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Boyd, Sean M <Sean.Boyd@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>  
**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Hi, Angie.

Attached please find OCC's comments on the updated guidance. Please let us know if you have any questions about our edits.

Thanks,

Renee

**Renée Tyndell Beaver**

Office of the Chief Counsel, FDA  
Food and Drug Division, OGC/HHS  
WO: 240-402-0142  
Cell: 240-247-7690  
[Renee.Beaver@fda.hhs.gov](mailto:Renee.Beaver@fda.hhs.gov)

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**From:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 3:53 PM  
**To:** Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>  
**Cc:** OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Boyd, Sean M <Sean.Boyd@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>  
**Subject:** FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Hi all,

Attached for your review and clearance is an update to CDRH's Guidance "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency". The attached version is redlined from the published guidance. We have left notes to the reviewers regarding why the revisions are being made to facilitate clearance.

Please contact me or Jacquie Gertz with any questions. You can reach me at (b) (6) .

Thank you,  
Angie

**Angela Krueger**  
*Deputy Director for Regulatory Policy*

**Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration**  
Tel: 301-796-6380  
[angela.krueger@fda.hhs.gov](mailto:angela.krueger@fda.hhs.gov)



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**From:** Manchester, Brittney [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=BD6CA86F5A3F43FFB295122F23A95770-BRITTNEY.MA]  
**Sent:** 4/1/2020 10:18:37 AM  
**To:** Caliguri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]  
**Subject:** FW: FDA EXPEDITIED REVIEW REQUESTED TONIGHT: Media Inquiry: Reuters - N95 fraud

**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](mailto:brittney.manchester@fda.hhs.gov)



---

**From:** Mednick, David <David.Mednick@fda.hhs.gov>  
**Sent:** Wednesday, April 1, 2020 9:40 AM  
**To:** Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>  
**Cc:** Raza, Mark <Mark.Raza@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>  
**Subject:** RE: FDA EXPEDITIED REVIEW REQUESTED TONIGHT: Media Inquiry: Reuters - N95 fraud

Hi Brittney,

The guidance is in the FDA clearance process. Once it clears FDA, we'll review your language, noting that you should circle back after the guidance is finalized in case changes were made at the HHS or OMB stages.

---

**From:** Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 8:55 AM  
**To:** Mednick, David <David.Mednick@fda.hhs.gov>  
**Cc:** OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Schulken, Susan <Susan.Schulken@fda.hhs.gov>; Pagan Motta, Monica <Monica.PaganMotta@fda.hhs.gov>; MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>  
**Subject:** RE: FDA EXPEDITIED REVIEW REQUESTED TONIGHT: Media Inquiry: Reuters - N95 fraud

Hi David,

I held on the media inquiries until the revised guidance posts today. When it does, I'd like to use the following in this media response and others we've received. We are also going to use this language to post on our website in an FAQ so we have somewhere public to point people too. I've tried to keep it as plain language as possible. Can you please let me know if it's approved?

While KN95 masks made in China are eligible for Emergency Use Authorizations (EUAs), these products can still be imported and used in the United States without an EUA. The FDA is not blocking KN95 mask importations. Without an EUA, however, the FDA cannot assure the performance and quality of KN95 masks due to fraudulent product that has come from China. Therefore, although not required, importers may want to take appropriate steps to verify the authenticity of these products. The FDA is ready and available to engage with importers to minimize disruptions during the importing process.

Thank you,  
Brittney

**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](mailto:brittney.manchester@fda.hhs.gov)



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**From:** Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]  
**Sent:** 3/24/2020 11:58:49 AM  
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]  
**CC:** Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Grogan, Joseph J. EOP/WHO [Joseph.J.Grogan@who.eop.gov]; Rom, Colin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221f4340d697dbd43ee27255fb-Colin.Rom]  
**Subject:** RE: Here's a paper for consideration

Jeff and Stacy, Thanks for the guidance here and I will follow up with Mt Sinai with an email and call now  
Anand

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 11:53 AM  
**To:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** RE: Here's a paper for consideration

(b) (5)



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**From:** Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>  
**Sent:** Tuesday, March 24, 2020 11:50 AM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>  
**Subject:** Re: Here's a paper for consideration

Anand,

Yes, fine to exercise enforcement discretion for this shipment. Early this morning the emergency use authorization for non--NIOSH N95 respirators was signed. Under the 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 because of the higher likelihood of receiving counterfeit product.

Therefore, please proceed with the shipment under enforcement discretion. If there is concern that the product should be under the umbrella emergency use authorization, we can probably do so with just some documentation that these respirators received marketing authorization from China NMPA. If not, nothing else to do.

Jeff

**From:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>

**Date:** March 24, 2020 at 11:18:33 AM EDT

**To:** Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>

**Cc:** Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>, Grogan, Joseph J. EOP/WHO <[Joseph.J.Grogan@who.eop.gov](mailto:Joseph.J.Grogan@who.eop.gov)>, Rom, Colin <[Colin.Rom@fda.hhs.gov](mailto:Colin.Rom@fda.hhs.gov)>

**Subject:** FW: Here's a paper for consideration

**Importance:** High

Jeff – I just got off the phone with Ken Davis, CEO of Mt Sinai. They have an acute shortage of N95 and 200+ employees who have tested positive and out of work. They have pinpointed a supply of KN95 in China and a private aircraft lined up to move a shipment. Can we consider temporary enforcement discretion here? I ran this by Stacy and she can work with us to operationalize. Please let me know your thoughts. Thanks, Anand

---

**From:** Grogan, Joseph J. EOP/WHO <[Joseph.J.Grogan@who.eop.gov](mailto:Joseph.J.Grogan@who.eop.gov)>

**Sent:** Monday, March 23, 2020 9:34 AM

**To:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Caliguiri, Laura (OS) <[Laura.Caliguiri@hhs.gov](mailto:Laura.Caliguiri@hhs.gov)>; Hahn, Julia A. EOP/WHO (b) (6) Rom, Colin F. EOP/OMB <[Colin.F.Rom@omb.eop.gov](mailto:Colin.F.Rom@omb.eop.gov)>

**Cc:** Bonner, Maria K. EOP/WHO <[Maria.K.Bonner@who.eop.gov](mailto:Maria.K.Bonner@who.eop.gov)>; Campana, Alexandra D. EOP/WHO <[Alexandra.D.Campana2@who.eop.gov](mailto:Alexandra.D.Campana2@who.eop.gov)>

**Subject:** Here's a paper for consideration

Guys can you take a look at this possible solution to shortages. We could do this for two months during the emergency... if there's a quickj and fast alternative, that's cool. Specifically, it was Mount Sinai that has a problem getting enough masks. Ken Davis. His email is (b) (6). His number is (b) (6)

---

**From:** Keagan.Lenihan@fda.hhs.gov [Keagan.Lenihan@fda.hhs.gov]  
**Sent:** 3/30/2020 10:02:22 PM  
**To:** Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]  
**CC:** Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]  
**Subject:** Re: Kn95s manufactured in China

Excellent. Thank you.

Sent from my iPhone

On Mar 30, 2020, at 9:48 PM, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

We're still unpacking this, but it sounds like there might not be a big difference in what we are saying—CDC is saying the KN95 might, in form, be an acceptable standard. And we have concerns about individual shipments coming b/c of risk of counterfeit, although people are still welcome to import the products. We just cannot assure quality/performance.

Working out some language with CDRH/Anand to use for media inquiries. More to come in AM!

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

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 7:36 PM  
**To:** Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
**Subject:** Fwd: Kn95s manufactured in China

What's are messaging as to why CDC is ok with one thing and FDA isn't?

Sent from my iPhone

Begin forwarded message:

**From:** "Gross, Karas" <Karas.Gross@fda.hhs.gov>  
**Date:** March 30, 2020 at 7:21:50 PM EDT  
**To:** "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: Kn95s manufactured in China

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**From:** Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 6:58 PM  
**To:** Gross, Karas <Karas.Gross@fda.hhs.gov>; McMillin, Virginia D. EOP/WHO <Virginia.D.McMillin@who.eop.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Brand, Anstice M (CDC) <atb6@cdc.gov>



**Cc:** Hodgson, Christopher M. EOP/OVP <(b) (6)>

**Subject:** RE: Kn95s manufactured in China

Under the 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.

---

**From:** Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>

**Date:** March 30, 2020 at 3:12:44 PM EDT

**To:** McMillin, Virginia D. EOP/WHO <[Virginia.D.McMillin@who.eop.gov](mailto:Virginia.D.McMillin@who.eop.gov)>, Pence, Laura (OS) <[Laura.Pence@hhs.gov](mailto:Laura.Pence@hhs.gov)>, Brand, Anstice M (CDC) <[atb6@cdc.gov](mailto:atb6@cdc.gov)>

**Cc:** Hodgson, Christopher M. EOP/OVP <(b) (6)> Paulos, Lauren <[Lauren.Paulos@fda.hhs.gov](mailto:Lauren.Paulos@fda.hhs.gov)>

**Subject:** RE: Kn95s manufactured in China

Adding Lauren.

We'll follow up soon.

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

**From:** McMillin, Virginia D. EOP/WHO <[Virginia.D.McMillin@who.eop.gov](mailto:Virginia.D.McMillin@who.eop.gov)>

**Sent:** Monday, March 30, 2020 3:09 PM

**To:** Pence, Laura (OS) <[Laura.Pence@hhs.gov](mailto:Laura.Pence@hhs.gov)>; Gross, Karas <[Karas.Gross@fda.hhs.gov](mailto:Karas.Gross@fda.hhs.gov)>; Brand, Anstice M (CDC) <[atb6@cdc.gov](mailto:atb6@cdc.gov)>

**Cc:** Hodgson, Christopher M. EOP/OVP <(b) (6)>

**Subject:** FW: Kn95s manufactured in China

Hi! Do yall have any background on the discrepancy between the CDC and FDA guidelines re: KN95s that you can share?

Thank you

Virginia Heppner McMillin

Special Assistant to the President

Office of Legislative Affairs

(b) (6)

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

**From:** McConnell, Kellie (Crapo) <[Kellie\\_McConnell@crapo.senate.gov](mailto:Kellie_McConnell@crapo.senate.gov)>

**Sent:** Monday, March 30, 2020 2:35 PM

**To:** McMillin, Virginia D. EOP/WHO <[Virginia.D.McMillin@who.eop.gov](mailto:Virginia.D.McMillin@who.eop.gov)>

**Subject:** Kn95s manufactured in China

Hey lady- we have a company in Idaho with existing contracts for CE/China kn95 masks. This weekend, CDC included these masks as acceptable alternatives for n95s. However, the FDA did not include the CE/China kn95s in its updated EUA. Because they aren't included in the FDA EUA, they don't have a code to get this shipment through customs. I've

flagged the discrepancy for FDA and CDC. The Idaho company sent the FDA a request for an EUA, but obviously the easiest thing would be for the FDA EUA to reflect the CDC guidelines.

Thanks for any help reconciling the differences!

Kellie

Sent from my iPhone

---

**From:** Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]  
**Sent:** 3/28/2020 8:58:28 PM  
**To:** Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]  
**CC:** Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mednick, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba9faf32217141efaf6904d00b795eb2-David.Medni]  
**Subject:** RE: KN95 Masks

Thanks for sharing.

---

**From:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Date:** March 28, 2020 at 8:49:08 PM EDT  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Mednick, David <David.Mednick@fda.hhs.gov>  
**Subject:** RE: KN95 Masks

Thanks, Stacy. I'm sure you already know this, but just in case, Suzanne Schwartz and CDRH have been working closely on the KN95 issues because this product has come up frequently in the FEMA Supply Chain TF PPE procurement effort. Suzanne has the most current background on this, but following is what was recently shared through the IMG (internal):

- According to NIOSH, KN-95s that are authorized by China meet similar standards to NIOSH certified N-95s. However, FDA did not list these products in its emergency use authorization due to challenges in determining the authenticity of imported product and we have already encountered fraudulent products identified as KN95s. FDA generally would not object to 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.
- FDA and CBP are working together to assess KN-95s as they come into US ports. But, as stated above, importers can greatly help by doing their due diligence before a product is even procured and shipped.

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Saturday, March 28, 2020 8:41 PM  
**To:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Cc:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>  
**Subject:** Fwd: KN95 Masks

Brooke FYI.

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Date:** March 28, 2020 at 8:40:33 PM EDT  
**To:** Mizelle, Chad (b) (6)

**Cc:** Stimson, Brian (OS) <[Brian.Stimson@hhs.gov](mailto:Brian.Stimson@hhs.gov)>

**Subject:** Re: KN95 Masks

My SMEs looked at this email chain and said:

(b) (5)

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**From:** Mizelle, Chad (b) (6)

**Date:** March 28, 2020 at 8:00:21 PM EDT

**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

**Subject:** Re: KN95 Masks

Stacy,

Thanks for all the helpful information. Would love to chat about your ideas for an efficient process. In the meantime, I'm going to press the FEMA team about these masks.

Best,

Chad

Chad Mizelle

(b) (6)

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

**Sent:** Saturday, March 28, 2020 7:36:31 PM

**To:** Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>; Mizelle, Chad (b) (6)

**Cc:** Lyons, Derek S. EOP/WHO <Derek.S.Lyons@who.eop.gov>; Ray, Paul J. EOP/OMB <Paul.J.Ray@omb.eop.gov>;

Bonner, Maria K. EOP/WHO <Maria.K.Bonner@who.eop.gov>; Stimson, Brian (OS) <Brian.Stimson@hhs.gov>

**Subject:** Re: KN95 Masks

**CAUTION:** This email originated from outside of DHS. DO NOT click links or open attachments unless you recognize and/or trust the sender. Contact your component SOC with questions or concerns.

Yes feel free to send them back to me. (b) (5)

(b) (5) Chad we should probably talk offline about what your understanding is of the process for routing those questions and getting them addressed by FDA. I have some thoughts on efficient process.

---

**From:** Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>

**Date:** March 28, 2020 at 7:31:49 PM EDT

**To:** Mizelle, Chad (b) (6)

**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Lyons, Derek S. EOP/WHO <Derek.S.Lyons@who.eop.gov>, Ray, Paul J. EOP/OMB <Paul.J.Ray@omb.eop.gov>, Bonner, Maria K. EOP/WHO <Maria.K.Bonner@who.eop.gov>

**Subject:** Re: KN95 Masks

Keep Me posted because I thought (b) (5)

Sent from my iPhone

On Mar 28, 2020, at 7:18 PM, Mizelle, Chad (b) (6) wrote:

This is very, very helpful. We found, as part of the DOJ Task Force, what I understand to be several pallets of KN95 masks with Chinese labeling in a warehouse in Atlanta — Initial indications are that the owner was hoarding them in apparent contravention of several anti-hoarding provisions. The ask to FEMA was to procure the masks, and they came back

saying that they could not procure the masks because they were not approved by the FDA. I'll go back to FEMA with this info.

Stacy—If they have any questions, mind if I defer them to you?

Chad Mizelle

(b) (6)

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**From:** Grogan, Joseph J. EOP/WHO <[Joseph.J.Grogan@who.eop.gov](mailto:Joseph.J.Grogan@who.eop.gov)>

**Sent:** Saturday, March 28, 2020 6:20 PM

**To:** Amin, Stacy

**Cc:** Mizelle, Chad; Lyons, Derek S. EOP/WHO; Ray, Paul J. EOP/OMB; Bonner, Maria K. EOP/WHO

**Subject:** Re: KN95 Masks

**CAUTION:** This email originated from outside of DHS. DO NOT click links or open attachments unless you recognize and/or trust the sender. Contact your component SOC with questions or concerns.

I also think specifically on the KN95s something was done. I think it was mentioned on a task force call. Stacy can you ask fda about that mask specifically? Chad I also might have Admiral P. Who is imbedded with fema who mentioned that they either just purchased a bunch for distribution or fda just allowed import of them so you might want to ask the fema team too.

Sent from my iPhone

On Mar 28, 2020, at 4:07 PM, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)> wrote:

Can you clarify what masks you are seeking to use and for what setting? We have issued two broad EUAs.

Under the NIOSH EUA:

1. Non-powered air-purifying particulate filtering facepiece respirators (FFRs) and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the NIOSH Certified Equipment List (CEL) for non-powered air purifying respirators with particular protection;
2. Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the NIOSH CEL for PAPRs with particular protection, and;

3. FFRS that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with mfrs storage conditions in strategic stockpiles (i.e. expired FFRs).

Under the non-NIOSH EUA:

1. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications from Australia, Brazil, Europe, Japan, Korea, or Mexico, and/or;
2. Disposable FFRs which have a marketing authorization in either Europe, Australia, Canada, or Japan.

All of these respirators are authorized for use by healthcare personnel in healthcare settings when used in accordance with CDC recommendations.

(b) (5)

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**From:** Mizelle, Chad (b) (6) >

**Sent:** Saturday, March 28, 2020 1:50 PM

**To:** Lyons, Derek S. EOP/WHO <[Derek.S.Lyons@who.eop.gov](mailto:Derek.S.Lyons@who.eop.gov)>

**Cc:** Paul Ray ([Paul.J.Ray@omb.eop.gov](mailto:Paul.J.Ray@omb.eop.gov)) <[paul.j.ray@omb.eop.gov](mailto:paul.j.ray@omb.eop.gov)>; Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

**Subject:** Re: KN95 Masks

Looping in Paul Ray and Stacy. I'm not quite sure what the process is, or if there are any available options. FEMA is currently buying dust masks, (b) (5)

Chad Mizelle

(b) (6)

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**From:** Lyons, Derek S. EOP/WHO (b) (6) >

**Sent:** Saturday, March 28, 2020 1:35 PM

**To:** Mizelle, Chad

**Subject:** Re: KN95 Masks

**CAUTION:**This email originated from outside of DHS. DO NOT click links or open attachments unless you recognize and/or trust the sender. Contact your component SOC with questions or concerns.

Exactly—can we (b) (5) :?

Sent from my iPhone

On Mar 28, 2020, at 1:31 PM, Mizelle, Chad (b) (6) wrote:

Apparently we can't use them because they aren't FDA approved. Just FYI

Chad Mizelle

(b) (6)



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**From:** Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]  
**Sent:** 3/30/2020 9:50:05 PM  
**To:** McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]  
**CC:** Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Courtney, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]  
**Subject:** RE: Global EUA document  
**Attachments:** 20200320 COVID19 EUAs.docx

Attached are recommended edits to the narrative portion of the list.

---

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 9:43 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Cc:** Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>  
**Subject:** RE: Global EUA document

Okay, a list of guidances we have issued a very high level description of them. I can make that in a separate document and start the clearance tomorrow, I recommend keeping this document moving so we can get it out. We could make it available on our website and then update with guidances, unless you prefer everything in one document. It will just take a bit more time to clear.

Liz and Michael, can you please add publicly known INDs to the list?

Thank you,

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 8:55 PM  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Cc:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>  
**Subject:** Re: Global EUA document

Agree on guidances. That would also be extremely helpful.

Sent from my iPhone

On Mar 30, 2020, at 8:52 PM, Amin, Stacy <Stacy.Amin@fda.hhs.gov> wrote:

(b) (5)

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 5:50 PM  
**To:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>  
**Subject:** RE: Global EUA document

Quick point of clarity, do we need to include the products that are listed in appendix b of the ventilator guidance or just explain what the guidance does? For ease, I am also including contact information for developers having trouble navigating our website.

---

**From:** Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Sent:** Monday, March 30, 2020 5:44 PM  
**To:** Mair, Michael <Michael.Mair@fda.hhs.gov>  
**Cc:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>  
**Subject:** Re: Global EUA document

+ Carly who has been working on this too.

Sent from my iPhone

On Mar 30, 2020, at 5:38 PM, Mair, Michael <Michael.Mair@fda.hhs.gov> wrote:

Stacy,

Hi. No worries...we completely understand the request and the urgency. We're happy to format an EUA page that makes the information more accessible.

We are assuming that the "Advisory Opinion" to industry that outlines when PREP coverage applies will include the fact the PREP Act coverage also extends to products being used under IND as well as any approved products being used for COVID-19.

Given that, we are thinking that in addition to an updated list of products that are covered by EUAs issued by FDA, information on products under IND may be helpful – especially when assessing MCMs for donation or procurement. In particular for drugs and therapeutics, we think it is important that it be messaged that products being studied under an IND also are covered under the PREP Act (our preference whenever possible from a development perspective is to go to the clinical trial route, not EUA). The list also should include messaging that approved/cleared products are covered under the PREP Act and, if possible, should be procured first. Ideally HHS's PREP Act page would maintain a list or link to an FDA page of PREP-Act eligible products.

We will add messaging along those lines for consideration. Let us know your thinking though. Thx -m

---

**From:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Sent:** Monday, March 30, 2020 9:32 AM  
**To:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>; Hinton, Denise <[Denise.Hinton@fda.hhs.gov](mailto:Denise.Hinton@fda.hhs.gov)>  
**Cc:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Courtney, Brooke <[Brooke.Courtney@fda.hhs.gov](mailto:Brooke.Courtney@fda.hhs.gov)>; Mair, Michael <[Michael.Mair@fda.hhs.gov](mailto:Michael.Mair@fda.hhs.gov)>; Sadove, Elizabeth <[Elizabeth.Sadove@fda.hhs.gov](mailto:Elizabeth.Sadove@fda.hhs.gov)>  
**Subject:** RE: Global EUA document

Thank you very much and Denise and team – I'm sorry if I came across harshly in the message below, I didn't mean to. I have just heard some feedback from people that are not familiar with our regulatory terminology, etc that they find the website hard for lay person to navigate (and these are people with zero experience and no spare time). So all I meant was for all the nontraditional parties that are reaching out to us about EUA coverage, it will be helpful for them to have products covered under EUAs listed in one document at one link that we can update.

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**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>  
**Sent:** Monday, March 30, 2020 7:55 AM  
**To:** Hinton, Denise <[Denise.Hinton@fda.hhs.gov](mailto:Denise.Hinton@fda.hhs.gov)>  
**Cc:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Courtney, Brooke <[Brooke.Courtney@fda.hhs.gov](mailto:Brooke.Courtney@fda.hhs.gov)>; Mair, Michael <[Michael.Mair@fda.hhs.gov](mailto:Michael.Mair@fda.hhs.gov)>; Sadove, Elizabeth <[Elizabeth.Sadove@fda.hhs.gov](mailto:Elizabeth.Sadove@fda.hhs.gov)>  
**Subject:** Re: Global EUA document

Thank you.

Sent from my iPhone

On Mar 30, 2020, at 7:53 AM, Hinton, Denise <[Denise.Hinton@fda.hhs.gov](mailto:Denise.Hinton@fda.hhs.gov)> wrote:

Good morning,

We will work to create/provide an user-friendly document that is in as real time as possible.

Thanks for the feedback.

Denise

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**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>  
**Sent:** Monday, March 30, 2020 7:12 AM  
**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>  
**Cc:** Hinton, Denise <[Denise.Hinton@fda.hhs.gov](mailto:Denise.Hinton@fda.hhs.gov)>; Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>; Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>; Courtney, Brooke <[Brooke.Courtney@fda.hhs.gov](mailto:Brooke.Courtney@fda.hhs.gov)>  
**Subject:** Re: Global EUA document

Agreed. Denise can we put these in categories and spell out what they are in ways people can understand them better?

Stacy, they are still somewhat technical. Not sure we will ever close the knowledge gap with the 20 somethings at FEMA that know nothing about Gov or FDA.

Sent from my iPhone

On Mar 29, 2020, at 10:28 PM, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)> wrote:

We need to do better. This website is hard for me to navigate and I have used it dozens of times. Given how many parties are reaching out that are not willing to do even 10 seconds of googling to get an answer, we need to make this really easy and user friendly for them or we will continue to just create more work for ourselves.

---

**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Date:** March 29, 2020 at 10:22:44 PM EDT

**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>, Hinton, Denise <[Denise.Hinton@fda.hhs.gov](mailto:Denise.Hinton@fda.hhs.gov)>

**Cc:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Courtney, Brooke <[Brooke.Courtney@fda.hhs.gov](mailto:Brooke.Courtney@fda.hhs.gov)>

**Subject:** Re: Global EUA document

We can put it in a document, but we add EUAs daily. Pls manage Denise. Who are we sending to?

Sent from my iPhone

On Mar 29, 2020, at 10:13 PM, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)> wrote:

(b) (5)  Nobody in the rest of the government is capable of navigating this website.

---

**From:** Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)>

**Date:** March 29, 2020 at 9:16:48 PM EDT

**To:** Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

**Cc:** Shah, Anand <[Anand.Shah@fda.hhs.gov](mailto:Anand.Shah@fda.hhs.gov)>, Hahn, Stephen <[SH1@fda.hhs.gov](mailto:SH1@fda.hhs.gov)>, Courtney, Brooke <[Brooke.Courtney@fda.hhs.gov](mailto:Brooke.Courtney@fda.hhs.gov)>

**Subject:** Re: Global EUA document

All COVID-19 EUAs are posted on this website: <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#2019-ncov>

Sent from my iPhone

On Mar 29, 2020, at 4:53 PM, Lenihan, Keagan <[Keagan.Lenihan@fda.hhs.gov](mailto:Keagan.Lenihan@fda.hhs.gov)> wrote:

Sir,

I am happy to have the team pull the global list of EUAs and update daily.

Thx,  
KL

Sent from my iPhone

On Mar 29, 2020, at 4:23 PM, Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)> wrote:

(b) (5)

Thank you.

\*\*\*\*\*

Stacy Cline Amin  
Chief Counsel  
Food and Drug Administration  
Deputy General Counsel  
Department of Health and Human Services

(b) (5)

(b) (5)

**Diagnostic Tests**

<b>Sponsor</b>	<b>Product (link to authorization letter)</b>	
Center for Disease Control and Prevention	[ HYPERLINK "https://www.fda.gov/media/134919/download" ]	
Wadsworth – New York State Public Health	[ HYPERLINK "https://www.fda.gov/media/135661/download" ]	
Roche Molecular Systems, Inc.	[ HYPERLINK "https://www.fda.gov/media/136046/download" ]	
Life Technologies (a part of Thermo Fisher Scientific, Inc.)	[ HYPERLINK "https://www.fda.gov/media/136113/download" ]	
Laboratory Corporation of America	[ HYPERLINK "https://www.fda.gov/media/136148/download" ]	
Hologic, Inc.	[ HYPERLINK "https://www.fda.gov/media/136153/download" ]	
Quest Diagnostics Infectious Disease, Inc.	[ HYPERLINK "https://www.fda.gov/media/136228/download" ]	
Quidel Corporation	[ HYPERLINK "https://www.fda.gov/media/136224/download" ]	
Abbott Molecular, Inc.	[ HYPERLINK "https://www.fda.gov/media/136255/download" ]	
GenMark Diagnostics, Inc.	[ HYPERLINK "https://www.fda.gov/media/136283/download" ]	
DIASORIN MOLECULAR LLC	[ HYPERLINK "https://www.fda.gov/media/136288/download" ]	
Primerdesign Ltd.	[ HYPERLINK "https://www.fda.gov/media/136306/download" ]	

INTERNAL DRAFT DELIBERATIVE

	]	
Cepheid	[ HYPERLINK "https://www.fda.gov/media/136316/download" ]	
Mesa Biotech Inc.	[ HYPERLINK "https://www.fda.gov/media/136345/download" ]	
BioFire Defense, LLC	[ HYPERLINK "https://www.fda.gov/media/136356/download" ]	
PerkinElmer, Inc.	[ HYPERLINK "https://www.fda.gov/media/136407/download" ]	
Avellino Labs USA	[ HYPERLINK "https://www.fda.gov/media/136450/download" \o "AvellinoCoV2 test - Letter of Authorization" ]	
BGI Genomics Co. Ltd.	[ HYPERLINK "https://www.fda.gov/media/136473/download" \o "Real-Time Fluorescent RT-PCR Kit for Detecting SARS-2019-nCoV (BGI Genomics Co. Ltd) - Letter of Authorization" ]	
Luminex Molecular Diagnostics, Inc.	[ HYPERLINK "https://www.fda.gov/media/136497/download" \o "NxTAG CoV Extended Panel Assay - Letter of Authorization" ]	
Abbott Diagnostics Scarborough, Inc.	[ HYPERLINK "https://www.fda.gov/media/136522/download" ]	

**Personal Protective Equipment Emergency Use Authorizations**

Sponsor	Product	What it Does
CDC	[ HYPERLINK "https://www.fda.gov/media/135763/download" ]	This action allows all purifying respirators that are approved by the CDC's National Institute for Occupational Safety and Health to be used in health care settings.
Stakeholders, including manufacturers, health care personnel, hospitals and others	[ HYPERLINK "https://www.fda.gov/media/136403/download" ]	Allows Personal Protective Equipment (PPE) that IS NOT NIOSH approved (including KN95 masks made in China) CAN be import and used in the United States.  Users of the products need to know that FDA cannot assure the performance and quality of these products because they did not undergo review.



		Although it is not required, importers of FFRs (Face Piece Respirators) and other face masks that are NOT under an EUA MAY want to take appropriate steps to verify the authenticity of the products they import.
Battelle	[ HYPERLINK "https://www.fda.gov/media/136529/download" ]	Allows a single respirator to be <b>recycled and reused up to 20 times</b> . Battelle is allowed scale up their operations to decontaminate about <b>120,000 respirators daily</b> and to use satellite locations operated by Battelle.

**Medical Devices**

Sponsor	Product	What it Does
<b>Manufacturers and other stakeholders</b>	[ HYPERLINK "https://www.fda.gov/media/136423/download" ]	Allows manufacturers to make small changes to ventilators, anesthesia gas machines that have been modified to be used as ventilators, and positive pressure breathing devices, ventilator accessories without going through the review process first to expedite getting products to patients faster.

**Therapeutics**

Sponsor	Product	What it Does
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(b) (4)

(b) (5)

**Questions about donating medical products and equipment to the US?**

- **If you have medical supplies or equipment to donate**, please provide the Federal Emergency Management Agency (FEMA) details on what you are offering through the [ HYPERLINK "https://www.fema.gov/covid19offers" ].
- **To sell medical supplies or equipment to the federal government**, please submit a price quote under the [ HYPERLINK "https://beta.sam.gov/opp/3e05e664e606486ca34d1a41b47ff0ff/view" ].

(b) (5)

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**From:** Krueger, Angela C [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=96C8F1F9D6A8481195BE2AA3147E0B4F-ACS]  
**Sent:** 4/1/2020 1:44:22 PM  
**To:** Mednick, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba9faf32217141efaf6904d00b795eb2-David.Medni]; Roth, Lauren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=52bfd08572694f269a20c508f3c04a03-Lauren.Roth]; Beaver, Renee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a77c584a71354ff78f66ccd04147c299-Renee.Beave]  
**CC:** OC OPPB OP RPMS [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f2e26c08c0a24020b0200a64ba43a096-OC OPPB OP]; Gertz, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e72dcaecd2034a5ba518c09d1ad19a89-Jacqueline.]; Chang, Cynthia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dcd7bfdbbd3401b8092b3f4cd157208-Cynthia.Cha]; Foy, Jonette [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7a71f13265e4c6db631bad25f224ce6-JRF]; Flannery, Ellen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f3a88f0ebdf24b898ccd4814707daedf-Ellen.Flann]; Hillebrenner, Elizabeth J [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a67a136982744bdbaada3648642e87a7-EJT]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Maisel, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a1173dcb42794e11805d85993d1f9797-WZM]; Shuren, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44335a0c2f834535bc8713dfd643905e-Jeff.Shuren]; Boyd, Sean M [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=19d7552ebc084e8594f876d7092a47b3-SBB]; Faris, Owen P [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d919c42856449589d2d24454b2f774e-OPF]; Dennis, Claire [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2f0121bf65bf48adb8077a2c49324223-Claire.Denn]; OCCRequests-COVID19 [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bcb756008a41407282a58324a7b5144a-OCCRequests]; Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]; Dupont, Jarilyn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ce4025bc43cc4505b2f29f2de33b7b36-JDUPONT]  
**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators  
**Attachments:** update - IIE\_Guidance\_COVID-19\_Face\_Masks\_L1 update V8 - redline to posted guidance.docx; update - IIE\_Guidance\_COVID-19\_Face\_Masks\_L1 update V8.docx

Hi all,

Thank you all for helping us move this forward. Attached are two documents. The first is the redline version of the guidance from the current version of the published guidance. The second is the response to OPLIA and OCC edits and comments.

Lauren – is this still going to HHS and OMB?

Thank you,  
Angie

---

**From:** Mednick, David <David.Mednick@fda.hhs.gov>  
**Sent:** Wednesday, April 01, 2020 1:23 PM

OC-MAY23-POSTING-000101

**To:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

**Cc:** OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Boyd, Sean M <Sean.Boyd@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>

**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Lauren's changes are fine with Renee, Claire, and me. Thanks.

---

**From:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>

**Sent:** Wednesday, April 1, 2020 12:58 PM

**To:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>

**Cc:** OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Boyd, Sean M <Sean.Boyd@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>

**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Hi Lauren,

Thanks for this proposal. CDRH is ok with the revised. We will send back a revised version addressing this and OCC's revisions/comments.

Angie

---

**From:** Roth, Lauren <Lauren.Roth@fda.hhs.gov>

**Sent:** Wednesday, April 01, 2020 12:50 PM

**To:** Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>

**Cc:** OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Boyd, Sean M <Sean.Boyd@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>

**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Angie and Renee (and others),

(b) (5)

(b) (5)

---

**From:** Roth, Lauren

**Sent:** Tuesday, March 31, 2020 11:36 PM

**To:** Beaver, Renee <[Renee.Beaver@fda.hhs.gov](mailto:Renee.Beaver@fda.hhs.gov)>; Krueger, Angela C <[Angela.Krueger@fda.hhs.gov](mailto:Angela.Krueger@fda.hhs.gov)>

**Cc:** OC OPPB OP RPMS <[OCOPPBOPRPMS@fda.hhs.gov](mailto:OCOPPBOPRPMS@fda.hhs.gov)>; Gertz, Jacqueline <[Jacqueline.Gertz@fda.hhs.gov](mailto:Jacqueline.Gertz@fda.hhs.gov)>; Chang, Cynthia <[Cynthia.Chang@fda.hhs.gov](mailto:Cynthia.Chang@fda.hhs.gov)>; Foy, Jonette <[Jonette.Foy@fda.hhs.gov](mailto:Jonette.Foy@fda.hhs.gov)>; Flannery, Ellen <[Ellen.Flannery@fda.hhs.gov](mailto:Ellen.Flannery@fda.hhs.gov)>; Hillebrenner, Elizabeth J <[Elizabeth.Hillebrenner@fda.hhs.gov](mailto:Elizabeth.Hillebrenner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Maisel, William <[William.Maisel@fda.hhs.gov](mailto:William.Maisel@fda.hhs.gov)>; Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>; Boyd, Sean M <[Sean.Boyd@fda.hhs.gov](mailto:Sean.Boyd@fda.hhs.gov)>; Faris, Owen P <[Owen.Faris@fda.hhs.gov](mailto:Owen.Faris@fda.hhs.gov)>; Mednick, David <[David.Mednick@fda.hhs.gov](mailto:David.Mednick@fda.hhs.gov)>; Dennis, Claire <[Claire.Dennis@fda.hhs.gov](mailto:Claire.Dennis@fda.hhs.gov)>; OCCRequests-COVID19 <[OCCRequests-COVID19@fda.hhs.gov](mailto:OCCRequests-COVID19@fda.hhs.gov)>; Schiller, Lowell <[Lowell.Schiller@fda.hhs.gov](mailto:Lowell.Schiller@fda.hhs.gov)>; Dupont, Jarilyn <[Jarilyn.Dupont@fda.hhs.gov](mailto:Jarilyn.Dupont@fda.hhs.gov)>

**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Angie,

Thanks for talking this through with me earlier. As we discussed, I'd like to get a better understanding of OCC's thinking on the approach for (b) (5) I'll circle back tomorrow with the team.

Thanks!

---

**From:** Beaver, Renee <[Renee.Beaver@fda.hhs.gov](mailto:Renee.Beaver@fda.hhs.gov)>

**Sent:** Tuesday, March 31, 2020 9:07 PM

**To:** Krueger, Angela C <[Angela.Krueger@fda.hhs.gov](mailto:Angela.Krueger@fda.hhs.gov)>

**Cc:** OC OPPB OP RPMS <[OCOPPBOPRPMS@fda.hhs.gov](mailto:OCOPPBOPRPMS@fda.hhs.gov)>; Gertz, Jacqueline <[Jacqueline.Gertz@fda.hhs.gov](mailto:Jacqueline.Gertz@fda.hhs.gov)>; Chang, Cynthia <[Cynthia.Chang@fda.hhs.gov](mailto:Cynthia.Chang@fda.hhs.gov)>; Foy, Jonette <[Jonette.Foy@fda.hhs.gov](mailto:Jonette.Foy@fda.hhs.gov)>; Flannery, Ellen <[Ellen.Flannery@fda.hhs.gov](mailto:Ellen.Flannery@fda.hhs.gov)>; Hillebrenner, Elizabeth J <[Elizabeth.Hillebrenner@fda.hhs.gov](mailto:Elizabeth.Hillebrenner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Maisel, William <[William.Maisel@fda.hhs.gov](mailto:William.Maisel@fda.hhs.gov)>; Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>; Boyd, Sean M <[Sean.Boyd@fda.hhs.gov](mailto:Sean.Boyd@fda.hhs.gov)>; Faris, Owen P <[Owen.Faris@fda.hhs.gov](mailto:Owen.Faris@fda.hhs.gov)>; Mednick, David <[David.Mednick@fda.hhs.gov](mailto:David.Mednick@fda.hhs.gov)>; Dennis, Claire <[Claire.Dennis@fda.hhs.gov](mailto:Claire.Dennis@fda.hhs.gov)>; OCCRequests-COVID19 <[OCCRequests-COVID19@fda.hhs.gov](mailto:OCCRequests-COVID19@fda.hhs.gov)>; Schiller, Lowell <[Lowell.Schiller@fda.hhs.gov](mailto:Lowell.Schiller@fda.hhs.gov)>; Roth, Lauren <[Lauren.Roth@fda.hhs.gov](mailto:Lauren.Roth@fda.hhs.gov)>; Dupont, Jarilyn <[Jarilyn.Dupont@fda.hhs.gov](mailto:Jarilyn.Dupont@fda.hhs.gov)>

**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Hi, Angie.

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<sup>[1]</sup> <https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html>.  
OC-MAY23-POSTING-000103

Attached please find OCC's comments on the updated guidance. Please let us know if you have any questions about our edits.

Thanks,

Renee

**Renée Tyndell Beaver**

Office of the Chief Counsel, FDA  
Food and Drug Division, OGC/HHS  
WO: 240-402-0142  
Cell: 240-247-7690  
[Renee.Beaver@fda.hhs.gov](mailto:Renee.Beaver@fda.hhs.gov)

---

**From:** Krueger, Angela C <[Angela.Krueger@fda.hhs.gov](mailto:Angela.Krueger@fda.hhs.gov)>

**Sent:** Tuesday, March 31, 2020 3:53 PM

**To:** Dennis, Claire <[Claire.Dennis@fda.hhs.gov](mailto:Claire.Dennis@fda.hhs.gov)>; Beaver, Renee <[Renee.Beaver@fda.hhs.gov](mailto:Renee.Beaver@fda.hhs.gov)>; OCCRequests-COVID19 <[OCCRequests-COVID19@fda.hhs.gov](mailto:OCCRequests-COVID19@fda.hhs.gov)>; Schiller, Lowell <[Lowell.Schiller@fda.hhs.gov](mailto:Lowell.Schiller@fda.hhs.gov)>; Roth, Lauren <[Lauren.Roth@fda.hhs.gov](mailto:Lauren.Roth@fda.hhs.gov)>; Dupont, Jarilyn <[Jarilyn.Dupont@fda.hhs.gov](mailto:Jarilyn.Dupont@fda.hhs.gov)>

**Cc:** OC OPPB OP RPMS <[OCOPPBOPRPMS@fda.hhs.gov](mailto:OCOPPBOPRPMS@fda.hhs.gov)>; Gertz, Jacqueline <[Jacqueline.Gertz@fda.hhs.gov](mailto:Jacqueline.Gertz@fda.hhs.gov)>; Chang, Cynthia <[Cynthia.Chang@fda.hhs.gov](mailto:Cynthia.Chang@fda.hhs.gov)>; Foy, Jonette <[Jonette.Foy@fda.hhs.gov](mailto:Jonette.Foy@fda.hhs.gov)>; Flannery, Ellen <[Ellen.Flannery@fda.hhs.gov](mailto:Ellen.Flannery@fda.hhs.gov)>; Hillebrenner, Elizabeth J <[Elizabeth.Hillebrenner@fda.hhs.gov](mailto:Elizabeth.Hillebrenner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Maisel, William <[William.Maisel@fda.hhs.gov](mailto:William.Maisel@fda.hhs.gov)>; Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>; Boyd, Sean M <[Sean.Boyd@fda.hhs.gov](mailto:Sean.Boyd@fda.hhs.gov)>; Faris, Owen P <[Owen.Faris@fda.hhs.gov](mailto:Owen.Faris@fda.hhs.gov)>

**Subject:** FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Hi all,

Attached for your review and clearance is an update to CDRH's Guidance "[Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency](#)". The attached version is redlined from the published guidance. We have left notes to the reviewers regarding why the revisions are being made to facilitate clearance.

Please contact me or Jacquie Gertz with any questions. You can reach me at (b) (6)

Thank you,  
Angie

**Angela Krueger**

*Deputy Director for Regulatory Policy*

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration  
Tel: 301-796-6380  
[angela.krueger@fda.hhs.gov](mailto:angela.krueger@fda.hhs.gov)



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**From:** Roth, Lauren [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH]  
**Sent:** 3/31/2020 11:27:12 PM  
**To:** Mednick, David [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ba9faf32217141efaf6904d00b795eb2-David.Medni]  
**CC:** Schiller, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77949b06919e4f91aa788e9a616c50c7-Lowell.Schi]  
**Subject:** FW: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators  
**Attachments:** update - IIE\_Guidance\_COVID-19\_Face\_Masks\_L1 update V7 (OCC Edits 3-31-20).docx

David,

(b) (5)

Thanks,

Lauren

*Internal, deliberative, privileged*

---

**From:** Beaver, Renee <Renee.Beaver@fda.hhs.gov>  
**Sent:** Tuesday, March 31, 2020 9:07 PM  
**To:** Krueger, Angela C <Angela.Krueger@fda.hhs.gov>  
**Cc:** OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Maisel, William <William.Maisel@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Boyd, Sean M <Sean.Boyd@fda.hhs.gov>; Faris, Owen P <Owen.Faris@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Dupont, Jarilyn <Jarilyn.Dupont@fda.hhs.gov>  
**Subject:** RE: FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

Hi, Angie.

Attached please find OCC's comments on the updated guidance. Please let us know if you have any questions about our edits.

Thanks,

Renee

**Renée Tyndell Beaver**  
Office of the Chief Counsel, FDA  
Food and Drug Division, OGC/HHS

WO: 240-402-0142  
Cell: 240-247-7690  
[Renee.Beaver@fda.hhs.gov](mailto:Renee.Beaver@fda.hhs.gov)

---

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**Sent:** Tuesday, March 31, 2020 3:53 PM  
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**Cc:** OC OPPB OP RPMS <[OCOPPBOPRPMS@fda.hhs.gov](mailto:OCOPPBOPRPMS@fda.hhs.gov)>; Gertz, Jacqueline <[Jacqueline.Gertz@fda.hhs.gov](mailto:Jacqueline.Gertz@fda.hhs.gov)>; Chang, Cynthia <[Cynthia.Chang@fda.hhs.gov](mailto:Cynthia.Chang@fda.hhs.gov)>; Foy, Jonette <[Jonette.Foy@fda.hhs.gov](mailto:Jonette.Foy@fda.hhs.gov)>; Flannery, Ellen <[Ellen.Flannery@fda.hhs.gov](mailto:Ellen.Flannery@fda.hhs.gov)>; Hillebrenner, Elizabeth J <[Elizabeth.Hillebrenner@fda.hhs.gov](mailto:Elizabeth.Hillebrenner@fda.hhs.gov)>; Caccomo, Stephanie <[Stephanie.Caccomo@fda.hhs.gov](mailto:Stephanie.Caccomo@fda.hhs.gov)>; Maisel, William <[William.Maisel@fda.hhs.gov](mailto:William.Maisel@fda.hhs.gov)>; Shuren, Jeff <[Jeff.Shuren@fda.hhs.gov](mailto:Jeff.Shuren@fda.hhs.gov)>; Boyd, Sean M <[Sean.Boyd@fda.hhs.gov](mailto:Sean.Boyd@fda.hhs.gov)>; Faris, Owen P <[Owen.Faris@fda.hhs.gov](mailto:Owen.Faris@fda.hhs.gov)>  
**Subject:** FRDTS No. 2020-263 - COVID Guidance Clearance - UPDATE to Masks/Respirators

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Please contact me or Jacquie Gertz with any questions. You can reach me at (b) (6)

Thank you,  
Angie

**Angela Krueger**  
*Deputy Director for Regulatory Policy*

**Office of Product Evaluation and Quality  
Center for Devices and Radiological Health  
U.S. Food and Drug Administration**  
Tel: 301-796-6380  
[angela.krueger@fda.hhs.gov](mailto:angela.krueger@fda.hhs.gov)



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**From:** Courtney, Brooke [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]  
**Sent:** 3/25/2020 4:34:26 PM  
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]  
**Subject:** RE: Need Guidance on importing N96 and/or KN95 Masks from China and/or Mexico

Thanks—I'm working on some other pressing issues, but will handle this one tonight.

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 4:32 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Cc:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Subject:** RE: Need Guidance on importing N96 and/or KN95 Masks from China and/or Mexico

Thank you!

---

**From:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 4:29 PM  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Cc:** Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
**Subject:** RE: Need Guidance on importing N96 and/or KN95 Masks from China and/or Mexico

Anything supply chain from external you can loop in Brooke Courtney (cc'd) who is working with FEMA

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Sent:** Wednesday, March 25, 2020 4:27 PM  
**To:** Shah, Anand <Anand.Shah@fda.hhs.gov>  
**Subject:** FW: Need Guidance on importing N96 and/or KN95 Masks from China and/or Mexico

What are we doing with random emails like this that aren't coming from the Dept or WH but from private parties?

---

**From:** johnp@ibuyxs.com <johnp@ibuyxs.com>  
**Sent:** Wednesday, March 25, 2020 4:01 PM  
**To:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Cc:** claudia@ibuyxs.com  
**Subject:** Need Guidance on importing N96 and/or KN95 Masks from China and/or Mexico

Hello Stacy,

We have many contacts overseas and in Mexico offering us both FDA and CE approved masks. We are registered on SAM, have our Duns #, and our Cage Code but no FDA registrations. What is required for us to import and what rules and regs need to be followed? We are likely to move large quantities to the states and hospitals that need them.



Thank you,

John

**John Pallazola**

Office: 800-290-5066 x707  
Mobile: (b) (6)

VP Director of Inbound Marketing  
iBuyXS  
Connecting OEM Excess With Customers That Need It!

 [JohnP@iBuyXS.com](mailto:JohnP@iBuyXS.com)  
 [www.iBuyXS.com](http://www.iBuyXS.com)  
 St. Pete, Florida



Cage Code: 8FF51



DUNS: 117323032



---

**From:** Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]  
**Sent:** 3/29/2020 12:17:28 PM  
**To:** Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]  
**Subject:** Re: KN95 Masks

Thanks

---

**From:** Amin, Stacy <Stacy.Amin@fda.hhs.gov>  
**Date:** March 28, 2020 at 4:31:33 PM EDT  
**To:** Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
**Subject:** FW: KN95 Masks

Want to make you aware of this note from the DHS GC and from the WH, Derek Lyons and Paul Ray. I will try to figure out what this is about.

---

**From:** Amin, Stacy  
**Sent:** Saturday, March 28, 2020 4:07 PM  
**To:** Mizelle, Chad <chad.mizelle@hq.dhs.gov>; Lyons, Derek S. EOP/WHO (b) (6)  
**Cc:** Paul Ray (Paul.J.Ray@omb.eop.gov) (b) (6); Grogan, Joseph J. EOP/WHO <Joseph.J.Grogan@who.eop.gov>  
**Subject:** RE: KN95 Masks

Can you clarify what masks you are seeking to use and for what setting? We have issued two broad EUAs.

Under the NIOSH EUA:

1. Non-powered air-purifying particulate filtering facepiece respirators (FFRs) and reusable respirators such as elastomeric half and full facepiece respirators, approved by NIOSH in accordance with 42 CFR Part 84 and listed on the NIOSH Certified Equipment List (CEL) for non-powered air purifying respirators with particular protection;
2. Other powered air purifying respirators (PAPRs) approved by NIOSH, in accordance with 42 CFR Part 84, and that are listed on the NIOSH CEL for PAPRs with particular protection, and;
3. FFRs that were NIOSH-approved but have since passed the manufacturers' recommended shelf-life, are not damaged, and have been held in accordance with mfrs storage conditions in strategic stockpiles (i.e. expired FFRs).

Under the non-NIOSH EUA:

1. Disposable FFRs that have been designed, evaluated, and validated to meet a given performance standard and have corresponding acceptable product classifications from Australia, Brazil, Europe, Japan, Korea, or Mexico, and/or;
2. Disposable FFRs which have a marketing authorization in either Europe, Australia, Canada, or Japan.

All of these respirators are authorized for use by healthcare personnel in healthcare settings when used in accordance with CDC recommendations.

(b) (5)

---

**From:** Mizelle, Chad <[chad.mizelle@hq.dhs.gov](mailto:chad.mizelle@hq.dhs.gov)>

**Sent:** Saturday, March 28, 2020 1:50 PM

**To:** Lyons, Derek S. EOP/WHO (b) (6) @

**Cc:** Paul Ray (b) (6) Amin, Stacy <[Stacy.Amin@fda.hhs.gov](mailto:Stacy.Amin@fda.hhs.gov)>

**Subject:** Re: KN95 Masks

Looping in Paul Ray and Stacy. I'm not quite sure what the process is, or if there are any available options. FEMA is currently buying dust masks, which are pretty low quality. So seems like this might be better than nothing...

Chad Mizelle

(b) (6)

---

**From:** Lyons, Derek S. EOP/WHO (b) (6)

**Sent:** Saturday, March 28, 2020 1:35 PM

**To:** Mizelle, Chad

**Subject:** Re: KN95 Masks

**CAUTION:** This email originated from outside of DHS. DO NOT click links or open attachments unless you recognize and/or trust the sender. Contact your component SOC with questions or concerns.

Exactly—can we (b) (5)

Sent from my iPhone

On Mar 28, 2020, at 1:31 PM, Mizelle, Chad <[chad.mizelle@hq.dhs.gov](mailto:chad.mizelle@hq.dhs.gov)> wrote:

Apparently we can't use them because they aren't FDA approved. Just FYI

Chad Mizelle

(b) (6)