Subject: FW: AO v. HHS, 20-1063
Date: Monday, November 21, 2022 at 12:30:19 PM Eastern Standard Time
From: Taylor Stoneman
To: FOIA
Attachments: FDA RELEASE - Final Release in response to AO Challenges.pdf

Hi there!

Can this production please be processed as responsive to a couple different FDA FOIA numbers? These are re-releases for our case 20-1063, and the attached PDF has several PDF files within it. All but one of the files are saved with the agency tracking number 2020-1977, and are responsive to MULTI-HHS-FDA-20-0415. But the last file in the set, which is saved with agency tracking number 2020-2523, is responsive to HHS-FDA-20-0498.

Related Litigation?: 20-1063

Response Status (Interim/Final): Final

Response Type (Docs/NRR/Glomar/Rejection): Docs

Legal Reviewer: Taylor

Lead Investigator: Kelsey (formerly Narintohn)

Let me know if you have any questions!

Thanks,
Taylor

From: Powell, Amy (CIV) <Amy.Powell@usdoj.gov>
Date: Friday, November 18, 2022 at 7:09 AM
To: Taylor Stoneman <taylor.stoneman@americanoversight.org>
Subject: RE: AO v. HHS, 20-1063

Taylor:

I am attaching here another, final production from FDA, as well as a rough draft of a Vaughn index of the other requested documents.

I believe we have a JSR due today in this matter, and I will send you a draft JSR later this morning. I believe only HHS and CMS still have outstanding consults; I'm working on getting estimates. I know HHS is close to done.

Amy

Amy Elizabeth Powell
Senior Trial Counsel, Federal Programs Branch

Civil Division, Department of Justice
150 Fayetteville St, Suite 2100
Raleigh, NC 27601
Phone: 919-856-4013
Email: amy.powell@usdoj.gov

From: Taylor Stoneman <taylor.stoneman@americanoversight.org>
Sent: Wednesday, November 02, 2022 6:27 PM
To: Powell, Amy (CIV) <Amy.Powell@usdoj.gov>
Subject: [EXTERNAL] Re: AO v. HHS, 20-1063

Thanks, Amy. Just want to make sure because I'm not seeing one in the PDF—is there a cover letter associated with this production?

Best,
Taylor

Taylor Stoneman (she/her)
Counsel
American Oversight
taylor.stoneman@americanoversight.org
(202) 848-1319

From: Powell, Amy (CIV) <Amy.Powell@usdoj.gov>
Date: Monday, October 31, 2022 at 7:31 AM
To: Taylor Stoneman <taylor.stoneman@americanoversight.org>
Subject: FW: AO v. HHS, 20-1063

Please see attached from FDA. My understanding is that they still have around a dozen consults outstanding.

Amy

Amy Elizabeth Powell
Senior Trial Counsel, Federal Programs Branch
Civil Division, Department of Justice
150 Fayetteville St, Suite 2100
Raleigh, NC 27601
Phone: 919-856-4013
Email: amy.powell@usdoj.gov

From: Fetalvo, Ninio J. EOP/OVP (b)(6)
Sent: 4/3/2020 6:34:41 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; DL OVP Comms COVID [DL.OVP.CommsCOVID@ovp.eop.gov]
CC: Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

ok

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 5:24 PM
To: DL OVP Comms COVID <(b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Bumping.

From: Felberbaum, Michael
Sent: Friday, April 03, 2020 2:35 PM
To: DL OVP Comms COVID <(b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Re-upping – looking to get back to the reporter ASAP.

From: Felberbaum, Michael
Sent: Friday, April 03, 2020 1:47 PM
To: DL OVP Comms COVID <(b)(6)
Cc: Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Hi all –

Flagging the below written responses related to the same Reuters story that HHS sent up content on yesterday.

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

FDA U.S. FOOD & DRUG ADMINISTRATION

From: Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>
Sent: Friday, April 03, 2020 12:29 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; OS - Interviews <interviews@hhs.gov>; ODOCPL Interviews (NIH/OD OCPL) ([b](6) <([b](6)>; ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Bialek, Stephanie M (CDC) <ilq8@cdc.gov>; CDC OADC Media Review <OADCMediaReview@cdc.gov>
Cc: OC OEA OMA-Press <OCOEAOMA-Press@fda.hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>
Subject: RE: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

Ok

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Friday, April 3, 2020 12:25 PM
To: OS - Interviews <interviews@hhs.gov>
Cc: OCOEAOMA-Press (FDA) <OCOEAOMA-Press@fda.hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS/ASPA) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS/ASPA) <Ryan.Murphy1@hhs.gov>
Subject: FDA Interview Request - Reuters - (Hydroxy)chloroquine EUA

****
ASPA Media Interview Request
****

Reporter: Aram Roston/Marisa Taylor

Organization: Reuters

Phone #(s): N/A

Subject: (Hydroxy)chloroquine EUA

Deadline: ASAP, Friday, April 3

Spokesperson: FDA Office of Media Affairs, in written response

Additional information: From what we understand, the story is focusing – similar to other stories from other outlets – that there's been pressure to allow for the use of these drugs for unapproved use and taking a deeper look at the development of the EUA. We are providing a general response (previously cleared for NYT) and then answers to specific questions. Reporter has also been working with ASPA/ASPR/BARDA on additional responses to specific questions in their lane.

Proposed Response:

As is true with any public health emergency, there's tremendous interest among all parties to identify and implement potential short- and long-term solutions to address this pandemic impacting people around the country and the world.

The EUA allowing these specific drugs to be donated to the Strategic National Stockpile and used for certain hospitalized patients with COVID-19 was prepared by expert FDA career staff and reflects extensive discussions with experts at CDC, NIH, and BARDA who are involved in pandemic response.

During the evaluation of the criteria under which to issue an EUA, it was determined, based on the scientific evidence available, that it is reasonable to believe that the specific drugs may be effective in treating COVID-19, and that, given there are no adequate, approved, or available alternative treatments, the known and potential benefits to treat this serious or life-threatening virus outweigh the known and potential risks when used under the conditions described in the EUA.

1. On what date did ASPR file a request for the EUA that the FDA issued on March 28?

The EUA reflected discussions over several days. The official request for the EUA was submitted on the same day that the EUA issued, on March 28.

2. What countries are being referred to here: "Based upon limited in-vitro and anecdotal clinical data in case series, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19."?

The reference to clinical data relates to studies in countries including China, Korea, and France. The number of trials listed on ClinicalTrials.gov for chloroquine or hydroxychloroquine interventions against COVID-19 has been increasing, another indication of the interest in these drugs in this setting. The national guidelines referenced include China and Korea.

3. Does the mention of "national guidelines" in the EUA letter include the CDC information for clinicians?

Information from the CDC, although not national guidelines, is a resource for clinicians on therapeutic options for COVID-19 patients, including chloroquine and hydroxychloroquine. Importantly, the EUA requires 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.

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: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/10/2020 2:02:44 PM
To: Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Manchester, Brittney [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bd6ca86f5a3f43ffb295122f23a95770-Brittney.Ma]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; DL OVP Comms COVID [DL.OVP.CommsCOVID@ovp.eop.gov]
CC: Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

It's fine. (b) (5) [redacted] it addresses everything well.

From: Block, Molly <Molly.Block@fda.hhs.gov>
Sent: Friday, April 10, 2020 2:01 PM
To: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID <(b)(6) [redacted] O'Malley, Devin M. EOP/OVP <Devin.M.O'Malley@ovp.eop.gov>
Cc: Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

Re-upping this inquiry. Can we get guidance? Thanks!

Happy to chat offline about this as well.

Molly

From: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>
Sent: Thursday, April 9, 2020 5:08 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; DL OVP Comms COVID <(b)(6) [redacted]
Cc: Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

Hello,

Checking in on review of the below.

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 | (b)(6) [redacted]
brittney.manchester@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Thursday, April 9, 2020 10:31 AM
To: DL OVP Comms COVID <(b)(6) [redacted]@[redacted]
Cc: Manchester, Brittney <Brittney.Manchester@fda.hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: FDA Media Request: CBS News 60 Minutes - PPE specific to COVID-19

Hello,

Sending the below request on behalf of my colleague Brittney.

Thanks,

Michael

Reporter: Sam Hornblower

Media Outlet: CBS News – 60 Minutes

FDA Spokespersons: FDA spokesperson via written response

Subject: PPE specific to COVID-19

Deadline: Today, April 9, 3PM

Expected place of publication (print, online, broadcast): Broadcast

Expected date of publication/airing: April 12

Background:
Sam is an associate producer at CBS News - 60 Minutes. The outlet is working on a story about PPE specific to COVID-19.

Questions:

1. What happened to the recalled products with Cardinal Health? We want to keep an eye on those Cardinal gowns - I assume they could be useful as isolation gowns at this point.

The FDA believes these gowns could be safe to use as isolation gowns. Because these gowns have been recalled it is not appropriate to use them in surgical or other interventional procedures, which would require re-conditioning of the gowns and appropriate sterilization. However, the recalled gowns may be used in drive through clinics, nursing homes and in hospitals in instances where sterility is not required or where surgery is not being performed.

We have been in contact with Cardinal Health and FEMA about donating the gowns, as-is, to the Strategic National Stockpile and using them appropriately. The gowns Cardinal Health had to donate – approximately 2 million that were subject to the recall – were relabeled, in bulk, for donation to the Strategic National Stockpile for distribution as non-surgical isolation apparel.

2. I want to see what we can learn about the issue of FDA efforts on the issue of global shortages of PPE. And states competing for it within the states, hoarding, how this is affecting the market etc.

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 during 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 conservations 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, are not authorized under an EUA so we have provided recommendations about the distribution and use of certain PPE that provides flexibility to manufacturers of many masks, gowns, and gloves. 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 devices 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.

3. And also any ongoing efforts related to watch for counterfeit PPE or misbranded PPE as hospitals turn to non traditional sourcing. The FDA considers the sale and promotion of fraudulent COVID-19 products to be a threat to the public health. We have an aggressive surveillance program that routinely monitors online sources for health fraud products, especially during a significant public health issue such as this one.

FDA has dedicated staff who closely monitor for fraudulent products and false or misleading product claims related to COVID-19, and we have already reached out to major retailers to ask for their help in monitoring their online marketplaces for fraudulent products with coronavirus and other pathogen claims. Products sold are subject to FDA investigation and potential enforcement action if they claim to prevent, treat, or cure COVID-19 but are not legally marketed for that intended use.

The FDA is aware of potential violations related to the sale and distribution of PPE during this pandemic. We've seen masks and gloves marketed online with specific claims that they will prevent COVID-19. FDA's Import Operations is also aware of number of COVID-19 Test Kits, other medical devices such as ventilators and other PPE coming in through Ports of Entry and International Mail that might come from illegitimate supply chain sources. Unfortunately, there are entities trying to exploit the expanded availability the agency is providing to suppliers to allow much-needed PPE where it is needed most. In one recent example, an import division examined a shipment of thousands of masks that bear a resemblance to those from a manufacturer that is registered and listed with the agency. But the evidence doesn't support that these masks are legitimate or that they come direct from the manufacturer, and they could be fake/substandard. There is no way to know that the consignee for that shipment would be getting those masks to where they are needed most (or if the consignee is trying to inappropriately profit off of the current situation).

Specific to respirators – For N95 respirators, we have seen examples of products that claim to be FDA-cleared that are not. FDA has cleared N95 surgical respirators and these respirators can be found by searching the FDA 510(k) database under procode MSH. FDA has also issued emergency use authorizations (EUAs) for NIOSH-approved respirators and certain non-NIOSH-approved respirators that can be used in health care settings and these authorized respirators are listed online – see:

- Appendix A
- Exhibit 1
- Two NIOSH lists from CDC:
  - >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=21C&contaminant=41&appdatefrom=&appdateto=&powered=&scbatype=&scbause=&privatelabel=<

In addition, the FDA did not list KN95 masks made per China's standards in its imported, non-NIOSH-approved March 24, 2020, EUA because of concerns about fraudulent products listed as KN95s. 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 KN95 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 health care 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 KN95 respirators. Although not required, if a KN95 respirator does not have an EUA, the FDA encourages importers to take the appropriate steps to verify the product's authenticity prior to importing.

FDA is not the only nation that cited issues with these products - we have since become aware that Dutch health authorities recalled 600,000 defective Chinese-made respirators.

As part of our effort to combat deceptive activity, we are working closely with major retailers who are monitoring their online marketplaces for fraudulent products with novel coronavirus and other pathogen claims. We are also monitoring retail stores, websites that appear to be legitimate pharmacies but are not, and social media platforms. The FDA will take action against unscrupulous actors who are marketing unlawful products related to this outbreak. Companies that fail to take corrective action immediately may be subject to Federal enforcement action, such as seizure or injunction.

For enforcement actions FDA has taken in regards to fraudulent products, please see: >https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products<

The FDA advises consumers to be cautious of websites and stores selling products that claim to prevent, treat, diagnose or cure COVID-19. Consumers can report any fraudulent COVID-19 products to: FDA-COVID-19-Fraudulent-Products@fda.hhs.gov

4. With respect to new American based companies coming into the picture who are rapidly jump in and get new factories online to alleviate the PPE shortage. I want to make sure that we don't highlight anything that isn't appropriate. These are regulated medical devices. If not done right it could be worse than nothing at all. So if there are examples of new facilities doing it right and getting FDA approval with correct specs etc. - PPE medical gear that is approved By FDA in record time so that they can get to hospitals that need them (since imports are all but foreclosed). Is there a way you could inform me about such examples?

FDA is working to provide flexibility and do everything we can to support patients, health care professionals, hospitals, medical product manufacturers and the public during this pandemic. The FDA is aggressive in providing maximum regulatory flexibility, while still providing crucial FDA oversight. We will continue to engage

with both traditional medical device manufacturers and other manufacturers about ways we can facilitate a ramping up of production of these vitally important medical devices.

We are communicating with companies interested in developing PPE, whether it is face shields, face masks, gowns, or other PPE, on how they may enter the US market. 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.

A few examples include:
1. 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 devices 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.
2. 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.
3. The Prisma HealthVentilation Expansion Splitter (VESper), which allows multiple patients to be treated by a single ventilator. See: >https://www.fda.gov/media/136528/download<

From: Fetalvo, Ninio (CMS/OC) [Ninio.Fetalvo@cms.hhs.gov]
Sent: 5/15/2020 12:00:33 PM
To: Foster, Timothy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=305ac986fff64e3abf3e57c20991bd33-HHS-Timothy]; Hayes, Jonathan H (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=09728a0143b84029ae2453fd78d6e02d-HHS-Jonatha]; Shuy, Bryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d06fd3793ef74049bbd7cd702b9ee4b0-HHS-Bryan.S]; Waters, Cicely (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fba91b63e0524bdda033348880b10ed0-HHS-Cicely.]; block.molly@epa.gov; Michael, Gretchen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9124cfb0a9114613a44e2269824f94e6-HHS-Gretche]; Kane, Elleen (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6233166344c4d4f8cb4057a8c91d30e-HHS-Elleen.]; Arbes, Sarah C (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1d762cd5e6ac41d0ae76ab5f15525359-HHS-Sarah.A]; Morse, Sara N (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4080ee237c084683ae674366e5cde21d-HHS-Sara.Mo]; Pence, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3f21407a02d44cd4901bcce26f9b3074-HHS-Laura.P]; Galatas, Kate (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0a0623b3cb34f86a2f6f9d14afe115e-HHS-kkg2-cd]; CDC IMS JIC OADC LNO -2 [eocevent202@cdc.gov]; Bonds, Michelle E (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=55bb1c6e16fc49c6840de58f10bce69f-HHS-meb0-cd]; Heldman, Amy B (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d1540bef81a43a594d474b947645915-HHS-evd4-cd]; McGowan, Robert K (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e6175b088b1d49a4bfa2de3862800d4a-HHS-omc2-cd]; Rich, Michawn M (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=74df5e4343744d2eb5ecfdb2e9dacf26-HHS-qig3-cd]; Brandt, Kimberly (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c27a38a5cf444a9eb4db07014d44f848-HHS-Kimberl]; Brookes, Brady (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be9bafe245ae491baa1c01e7e03ad9e4-HHS-Brady.B]; Corry, Thomas (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=231d7059d86a4849b57446fb3b682a17-HHS-Thomas.]; Bell, Damian (CMS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=786ee55e696149b1a3aee1be64e83e5b-HHS-Damian.]; Brady, William (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a0af371df94b4fbeef7821e5892048-HHS-William]; Callahan, Kenneth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ec339fe2bb494b829a3cb4b638466afb-HHS-Kenneth]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Trueman, Laura (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9385c36713d64340ac51bc3e72864402-HHS-Laura.T]; Johnston, Darcie (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0e6d7dbb72d4d6eb84029c0547f7458-HHS-Darcie.]; Stannard, Paula (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=447102489a24495bb9004e524dda1589-HHS-Paula.S]; Conrad, Patricia L (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e30cd6224aeb49c795844f43fd78a049-HHS-conradp]; Billet, Courtney R (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT)/cn=Recipients/cn=04ddfe30e6154dd5ab720f23eb6070df-HHS-billetc]; Shuy, Caitrin (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=875ab76b6ae34c4cad510d8e5ceddf9b-HHS-Caitrin]; Stover, Kathy A (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b2c949970bc3434e8e0b42fd9404e774-HHS-kathy.s]; Routh, Jennifer M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e8ec9d097ff40ec9672a45be2a7d906-HHS-jennife]; Heck, Mia (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=656b2fa5aca84a18851397d417a16672-HHS-Mia.Hec]; Sherman, Jennifer (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=96ea669491654aba8d4ea6816279e040-HHS-Jennife]; Kellogg, Rachel (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6dc3e53a06f5451cad9facbb50d54576-HHS-Rachel.]; Zebley, Kyle (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d79ac6af2e1b49089fca453b39ebddde-HHS-Kyle.Ze]; Stimson, Brian (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=21fcf1b527694276af1ccdb7db495042-HHS-Brian.S]; Jenny, Brenna (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b9c67f9e773345d99578e032e2e8b5a6-HHS-Brenna.]; Schaeffer, Alison M (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4141e15908124849b7b905ba381abe85-HHS-Alison.]; Thomas, Gloria D (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9198d045d3b247779f604deb26d8a2e5-HHS-Gloria.]; Fulmer, Brendan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3a4f4f84b75243b3af90cf1ea4fe1ada-HHS-Brendan]; Ezernack, Paige (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=872e1cb77bfe440596caae115cd6515c-HHS-Paige.E]; Myles, Renate H (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=04a3e5f0ac384bd6b70bd9cdee9082f2-HHS-mylesr-]; Burklow, John T (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20d9290a05474f989153cf26a5a4e669-HHS-Burklow]; Fine, Amanda B (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2df9b8b64006465d943d2f283ad87d1d-HHS-amanda.]; Fritz, Craig M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aae2df341fec455db972cce10f0749e5-HHS-craig.f]; Wojtowicz, Emma M (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc3ba2cdc9394d43af6d048bfd568b69-HHS-emma.wo]; Akinso, Woleola O (NIH) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd2eb000f5743ef81d334a38b32b4bd-HHS-akinsow]; Beckham, Tammy (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8b3c038e4917469dbb5666f0464192b3-HHS-Tammy.B]; Avula, Deepa (SAMHSA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1769053a2788410c9a49686112266ad9-HHS-Deepa.A]; Lepore, Loretta A (CDC) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=713d163ed33643caa6caec3a00adf141-HHS-phf7-cd]; Thorman, Caroline (ACF) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=61ab62aed42f45c4bdd1bd5419b5afcc-HHS-Carolin]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]; Marks, Caryn L (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e8a41c617994afa80efdda08b4c6053-HHS-Caryn.M]; Overstreet, Elizabeth (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=425b9f564782488395620134c9bc776f-HHS-Elizabe]

CC: ASPA-Deputies [ASPA-Deputies@hhs.gov]; Bird, Catherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=add7a78c8cec414c963d6b8213b7598a-HHS-Catheri]; Brennan, Patrick (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d4e87181146141b1ba0978553d9ff156-HHS-Patrick]

Subject: RE: FOR REVIEW BY NOON TOMORROW: HHS FACTSHEET 5.15

Attachments: HHS fact sheet WH 5.15 cms.docx

HHS fact sheet
WH 5.15 cms.docx

CMS edits attached.

CONFIDENTIAL. DELIBERATIVE. PRE-DECISIONAL.

From: Foster, Timothy (OS/ASPA) <Timothy.Foster@hhs.gov>
Sent: Thursday, May 14, 2020 10:08 PM
To: Hayes, Jonathan (OS/ASPR/IO) <Jonathan.Hayes@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Waters, Cicely (OS/ASPR/OEA) <Cicely.Waters@hhs.gov>; block.molly@epa.gov; Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>; Arbes, Sarah (HHS/ASL) <Sarah.Arbes@hhs.gov>; Morse, Sara (HHS/ASL) <Sara.Morse@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Galatas, Kate (CDC/OD/OADC) <kkg2@cdc.gov>; CDC IMS JIC OADC LNO -2 <eocevent202@cdc.gov>; Bonds, Michelle E. (CDC/OD/OADC) <meb0@cdc.gov>; Heldman, Amy B. (CDC/OD/OADC) <evd4@cdc.gov>; McGowan, Robert (Kyle) (CDC/OD/OCS) <omc2@cdc.gov>; Rich, Michawn (CDC/OD) <qig3@cdc.gov>; Brandt, Kimberly (CMS/OA) <Kimberly.Brandt1@cms.hhs.gov>; Brookes, Brady (CMS/OA) <Brady.Brookes@cms.hhs.gov>; Corry, Thomas (CMS/OA) <Thomas.Corry@cms.hhs.gov>; Bell, Damian (CMS/OC) <Damian.Bell@cms.hhs.gov>; Brady, Will (HHS/IOS) <William.Brady@hhs.gov>; Callahan, Kenneth (HHS/IOS) <Kenneth.Callahan@hhs.gov>; Caliguiri, Laura (FDA/OC) <Laura.Caliguiri@fda.hhs.gov>; Felberbaum, Michael (FDA/OC) <Michael.Felberbaum@fda.hhs.gov>; Caccomo, Stephanie (FDA/OC) <Stephanie.Caccomo@fda.hhs.gov>; Trueman, Laura (HHS/IEA) <Laura.Trueman@hhs.gov>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Conrad, Patricia (NIH/NIAID) [E] (b)(6) >; Billet, Courtney (NIH/NIAID) [E] (b)(6) ; Shuy, Caitrin (HHS/ASFR) <Caitrin.Shuy@hhs.gov>; Stover, Kathy (NIH/NIAID) [E] (b)(6) >; Routh, Jennifer (NIH/NIAID) [E] <(b)(6) >; Heck, Mia (HHS/OASH) <Mia.Heck@hhs.gov>; Sherman, Jennifer (HHS/OASH) <Jennifer.Sherman@hhs.gov>; Kellogg, Rachel (HHS/OASH) <Rachel.Kellogg@hhs.gov>; Zebley, Kyle (HHS/OS/OGA) <Kyle.Zebley@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>; Jenny, Brenna (HHS/OGC) <Brenna.Jenny@hhs.gov>; Schaeffer, Alison (HHS/OS/OGA) <Alison.Schaeffer@hhs.gov>; Thomas, Gloria (HHS/OS/OGA) <Gloria.Thomas@hhs.gov>; Fulmer, Brendan (HHS/IOS) <Brendan.Fulmer@hhs.gov>; Ezernack, Paige (OS/ASPR/SPPR) <Paige.Ezernack@hhs.gov>; Myles, Renate (NIH/OD) [E] <mylesr@mail.nih.gov>; Burklow, John (NIH/OD) [E] (b)(6) >; Fine, Amanda (NIH/OD) [E] <(b)(6) ; Fritz, Craig (NIH/OD) [E] (b)(6) >; Wojtowicz, Emma (NIH/OD) [E] <(b)(6) >; Akinso, Woleola (NIH/OD) [E] <(b)(6) ; Beckham, Tammy (HHS/OASH) <Tammy.Beckham@hhs.gov>; Avula, Deepa (SAMHSA/OFR) <Deepa.Avula@samhsa.hhs.gov>; Lepore, Loretta (CDC/OD/OCS) <phf7@cdc.gov>; Thorman, Caroline (ACF) <Caroline.Thorman@acf.hhs.gov>; Fetalvo, Ninio (CMS/OC) <Ninio.Fetalvo@cms.hhs.gov>; Block, Molly (FDA/OC) <Molly.Block@fda.hhs.gov>; Marks, Caryn (HHS/IEA) <Caryn.Marks@hhs.gov>; Overstreet, Elizabeth (OS/ASFR) <Elizabeth.Overstreet@hhs.gov>
Cc: ASPA-Deputies <ASPA-Deputies@hhs.gov>; Bird, Catherine (OS/IOS) <Catherine.Bird@hhs.gov>; Brennan, Patrick (OS/ASPA) <Patrick.Brennan@hhs.gov>
Subject: FOR REVIEW BY NOON TOMORROW: HHS FACTSHEET 5.15

All,

Attached is a cumulative fact sheet ASPA is compiling for the White House that contains key actions taken by HHS during the COVID-19 outbreak. This information was sourced from publicly-available information/cleared language and feedback from folks on this thread.

As the subject line suggests, this is a fact sheet of key actions/major items from the Department and not intended to be an exhaustive list. Everyone is invited to submit edits but please be mindful when you are submitting additions on behalf of your op/staff-div that we may only be able to include a few additional items from each division.

Friendly reminder - this document will be circulated to this thread each Thursday for updates/comments. If you would like to designate a single point of contact for your op/staff div to handle this inquiry in the future, please let Patrick Brennan and me know.

Please respond with any updates, comments, or edits to Patrick Brennan and me by 12:00 PM noon, tomorrow, May 15.

<< File: HHS fact sheet WH 5.15.docx >>

Timothy Foster
Advisor, Strategic Communications
Office of the Assistant Secretary for Public Affairs
U.S. Department of Health and Human Services
Timothy.Foster@HHS.Gov
(b)(6) [redacted]

Predecisional/deliberative communication

From: Fetalvo, Ninio J. EOP/OVP [(b)(6)]
Sent: 4/22/2020 3:30:38 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID [(b)(6) Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: Re: FOR INPUT BY 6 PM: WSJ Inquiry for FDA on groups influencing COVID policy/actions

Ok

—
Ninio J.H. Fetalvo
Office of the Vice President
(b)(6)

On Apr 22, 2020, at 3:26 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Seeking input/clearance by 6 p.m. for WSJ is working on a story about a group of scientists led by Tom Cahill in Boston, calling themselves "scientists to stop covid-19", and their deep work behind the scenes to influence policy related to the pandemic. The upshot of the story is that this group is helping governmental entities, including the FDA, slash red tape. The story is not focused on FDA, but likely will have some mention.

Proposed FDA response (we are not going to confirm/discuss any specifics he raises):

The response to the COIVD-19 pandemic is an all-hands-on-deck approach. The FDA has made clear from the beginning that it will work collaboratively with regulated industry to provide flexibility and advice to assist with work related to, or impacted by, this public health emergency and has done just that across a variety of areas we regulate.

Additional information from the reporter for your awareness:

The reporter understands the group (which includes former Merck CEO Ed Scolnick) has had many conversations with the FDA, including with Janet Woodcock and Stephen Hahn. They've also had influence with some changes related to FDA policy and getting the FDA to speed up approval of drugs/manufacturing. In particular, in the case of Regeneron, the group asked Tommy Hicks Jr. (co-chair of the RNC) to help get Renegeron permission to move some manufacturing to Limerick (Ireland) so they would have more capacity in the U.S. for covid drugs. This would have been a months-long approval process, but after Mr. Hicks got involved, the FDA called Regeneron the same day and said they would have permission. The reporter did note that the group, particularly Mr. Scolnick, was frustrated with the pace of the FDA early

on. He said, on a call with FDA staff, a few weeks ago: “You don't know a f---ing thing you’re talking about. You’re the problem here."

Thanks!

Michael

Michael Felberbaum
Senior Advisor

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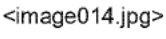

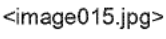

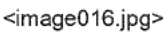

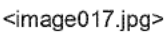

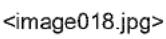

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/10/2020 10:56:20 PM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID (b)(6) v]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Block, Molly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e32ca68078848889751e7ec26910142-Molly.Block]
Subject: Re: Inquiry from NBC on Blood Donations

(b) (5)

Besides that this is fine

Sent from my iPhone

On Apr 10, 2020, at 8:08 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Checking in on this inquiry/response.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: April 10, 2020 at 6:37:52 PM EDT
To: 'DL OVP Comms COVID' <(b)(6)
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>, Hall, Bill (OS) <bill.hall@hhs.gov>, Robinson, Michael J (OS) <michael.robinson@hhs.gov>, Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>, McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Block, Molly <Molly.Block@fda.hhs.gov>
Subject: RE: Inquiry from NBC on Blood Donations

Reupping this plus another follow-up response to a Q about whether blood banks can implement immediately (some say they can't because they are waiting for the FDA, but that isn't true):

(b) (5)

From: Felberbaum, Michael
Sent: Friday, April 10, 2020 4:30 PM
To: DL OVP Comms COVID <(b)(6)
Cc: Murphy, Ryan (OS) <Ryan.Murphy1@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; McKeogh, Katherine (OS) <Katherine.McKeogh@hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>
Subject: Inquiry from NBC on Blood Donations

Hi,

NBC News is doing a story for its website regarding blood donations and recent changes by FDA. Local and national blood donation organization told them that the implementation process of the new guidance would take approximately three months. All said they have been experiencing outrage from newly eligible donors who attempt to donate, believing the new FDA guidance would immediately go into effect. Some blood centers say that the FDA guidance has put them in a difficult position by creating public expectation of immediate effectiveness and that there are additional steps that require FDA involvement in order to implement these changes.

- Can the FDA provide comment in response to the blood donation centers and why the agency has not emphasized that newly eligible donors would not be able to donate immediately?

- Additionally, we've been told that the implementation involves updating the FDA-controlled computer system which is used to screen donors who were previously deferred under the old guidelines. Is it true that the FDA controls the approvals and rejections of donors at blood centers? If so, has the FDA updated this software? If not, when do they plan on updating this software?

- Lastly, can the agency comment on its use of "immediate implementation" in the April 2nd press release? Does this language infer that the new guidelines should immediately be put in practice? Is there anything that can be done to expedite the process of implementation?

The below has been cleared by FDA and we are past the reporter's 4pm deadline – please let us know if we are OK to send..

The FDA's revised guidance documents were published for immediate implementation to address the urgent and immediate need for blood and blood components that has resulted from the COVID-19 pandemic. Therefore, once these recommendations were published, blood establishments implement them as soon as feasible.

We understand that blood establishments that intend to implement the new recommendations would need to update both their donor history questionnaires to screen donors consistent with the new recommendations and their procedures to now accept donors who were previously deferred. Blood establishments may also need to make changes to their blood establishment computer software which is used to manufacture blood components, and this process can take time.

We are hopeful that blood collectors will work expeditiously to make the changes needed to implement the modified recommendations so that they may begin collecting blood and blood products under these recommendations as quickly as possible. The FDA is available and willing to work with them as appropriate to assist them.

As noted in the FDA's April 2, 2020, statement announcing the availability of the revised guidance documents, blood establishments are not required to implement the changes in the FDA recommendations. Under the FDA's Good Guidance Practice regulations set forth in 21 CFR 10.115, when a guidance is issued for "immediate implementation," the guidance is being implemented without prior public comment, though we note that anyone can submit comments on any guidance documents after they are implemented.

Michael

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

From: O'Malley, Devin M. EOP/OVP [Devin.M.O'Malley@ovp.eop.gov]
Sent: 4/8/2020 2:52:33 AM
To: Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: DL OVP Comms COVID [(b)(6) [redacted]]; Oakley, Caitlin B (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b8feed045e954557aa1e0052f925865f-HHS-Caitlin]; McKeogh, Katherine (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3facab3fd03480f8553892121fd2009-HHS-Katheri]; Murphy, Ryan (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2c844c911312452e901760ebdd0f3820-HHS-Ryan.Mu]; Hall, Bill (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Robinson, Michael J (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4118fde5239947c6bccbdbd4cb7488fa-HHS-michael]
Subject: Re: Newsweek Inquiry on Hydroxychloroquine

Ok

Sent from my iPhone

On Apr 7, 2020, at 10:53 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Hi all,

Newsweek just reached out for a story the reporter is planning to submit within the next hour. The reporter says the story is about President Trump's statements that hydroxychloroquine could be an excellent treatment for COVID-19 and is asking if the FDA working towards approving hydroxychloroquine for that purpose?

Suggest sharing the following information both on the record and on background.

ON THE RECORD:
As is true with any public health emergency, there's tremendous interest among all parties to identify and implement potential short- and long-term solutions to address this pandemic impacting people around the country and the world.

The FDA has been working closely with other government agencies and academic centers that are investigating the use of the drug hydroxychloroquine and chloroquine, which are already approved for treating malaria, lupus and rheumatoid arthritis, to determine whether these drugs can be used to treat patients with mild-to-moderate COVID-19 and potentially reduce the duration of symptoms, as well as viral shedding, which can help prevent the spread of disease. Studies are underway to determine the efficacy in using these drugs to combat COVID-19.

BACKGROUND:
From the FDA perspective, with few exceptions, healthcare providers may choose to prescribe or use a legally marketed drug for other uses immediately when they judge that it is medically appropriate for their patient. The CDC has provided Information for Clinicians on Therapeutic Options for COVID-19 Patients.

Hydroxychloroquine sulfate and chloroquine phosphate are oral prescription drugs approved to treat malaria and other diseases. Although there are no currently approved treatments for COVID-19, both drugs have shown activity in laboratory studies against coronaviruses, including SARS-CoV-2 (the virus that causes COVID-19). Anecdotal reports suggest that these drugs may offer some benefit in the treatment of hospitalized COVID-19 patients. Clinical trials are needed to provide scientific evidence that these treatments are effective.

On March 28, 2020, the FDA issued an 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.

During the evaluation of the criteria under which to issue an EUA, it was determined, based on the scientific evidence available, that it is reasonable to believe that the specific drugs may be effective in treating COVID-19, and that, given there are no adequate, approved, or available alternative treatments, the known and potential benefits to treat this serious or life-threatening virus outweigh the known and potential risks when used under the conditions described in the EUA.

Thank you,

Michael

Michael Felberbaum
Senior Advisor

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

<image013.png>

<image014.jpg>

<image015.jpg>

<image016.jpg>

<image017.jpg>

<image018.jpg>

From: Hahn, Stephen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A0AFAC0CFA3C4B98913833E38A036E9F-STEPHEN.HAH]
Sent: 4/6/2020 5:37:22 PM
To: Birx, Deborah L. EOP/NSC [Deborah.L.Birx@nsc.eop.gov]
Subject: Re: Finger sticks

Thanks. We wanted to make sure that we didn't run out of supply.
S

From: Birx, Deborah L. EOP/NSC <Deborah.L.Birx@nsc.eop.gov>
Date: April 6, 2020 at 5:35:58 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Subject: Re: Finger sticks

We used any in Africa.

Sent from my iPhone

On Apr 6, 2020, at 5:29 PM, Hahn, Stephen <SH1@fda.hhs.gov> wrote:

FYSA

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: April 3, 2020 at 1:16:36 PM EDT
To: Giroir, Brett (OS) <Brett.Giroir@hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

We identified 92 firms that are manufacturers or contract manufacturers for blood lancets from information in our Registration & Listing database. Of these 92 firms, 11 are domestic and 82 are foreign. The attachment provides information on each of these firms including addresses, listing numbers, proprietary brand names and official correspondent contact information. We do not have information on production volume. These products are generally Class I, not subject to FDA review.

Please let me know if you need anything else.

From: Shuren, Jeff
Sent: Friday, April 3, 2020 7:55 AM
To: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

All blood lancets should be usable but I'm double checking and will let you know if some can't be used. We are also pulling together a list of manufacturers from our database. The other products that will be in high demand are vacutainer tubes for venous blood draws as well as PPE.

The list below provides manufacturers of serology tests we plan to assess. All said they can currently make the amounts listed below except for Cellex who will have tests available in about (b) (4). Abbott will have lateral flow test ready for review around mid(b) (4) and automated serology around end of(b) (4)but don't have production times yet. Roche said they will give us projections late (b) (4).

Appendix A: Individual Point of Care Lateral Flow Tests

All information in the tables below is from the manufacturer and has not been reviewed by FDA.

All manufacturers produce combined IgM and IgG lateral flow serology tests and have expressed a willingness to provide tests for independent evaluation.

Manufacturer Name	Test Name	Regulatory Authorizations	Estimated Ready to Ship to US	Estimated Weekly Production for US	Sample type
Cellex	qSARS-CoV-2 IgG/IgM Rapid Test		(b) (4)		serum, plasma
BioMedomics (through BD / Henry Schein)	COVID-19 IgM-IgG Rapid Test				fingerstick
Getein Biotech, Inc.	One Step Test for Novel Coronavirus(2019-nCoV) IgM/IgG antibody (Colloidal Gold)	CE-IVD			fingerstick, whole blood, serum, plasma
Nanjing Liming Bio-products Co.,Ltd	SARS-CoV-2 IgM/IgG Antibody Rapit Test	CE-IVD			whole blood, serum, plasma
(b) (4), (b) (5)					
Hangzhou Alltest Biotech Co.,Ltd	AllTest 2019-nCoV IgG/IgM Rapid Test Cassette AllTest COVID IgG/IgM Rapid Test Dipstick	CE-IVD, Brazil ANVISA, Guatemala Registration, Ukraine Registration	(b) (4)		fingerstick, whole blood, serum, plasma
(b) (4), (b) (5)					

Manufacturer Name	Test Name	Regulatory Authorizations	Estimated Ready to Ship to US	Estimated Weekly Production for US	Sample type
(b) (4), (b) (5)					
Testsea Biotechnology	One Step SARS-CoV2 (COVID-19) IgG/IgM Test	CE Mark, DAkks ISO13485	(b) (4)		fingerstick, whole blood, serum, plasma. The kits provide material for fingerstick.
(b) (4), (b) (5)					
Chembio Diagnostic Systems, Inc.	DPP COVID-19 IgM/IgG System	ANVISA	(b) (4)		fingerstick, whole blood, serum, plasma
(b) (4), (b) (5)					
Total			(b) (5)		

From: Giroir, Brett (HHS/OASH) <Brett.Giroir@hhs.gov>
Sent: Friday, April 3, 2020 7:29 AM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Beckham, Tammy (OS) <Tammy.Beckham@hhs.gov>
Subject: RE: Finger sticks

Thank you
Does anyone have the firm info on IgM IgG time course?
And I assume we (b) (5)

Brett P. Giroir, MD
ADM, US Public Health Service
Assistant Secretary for Health (ASH)
200 Independence Avenue, SW
Washington, DC 20201
Office Phone: 202-690-7694

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Friday, April 3, 2020 7:26 AM