Thank you, all!

Here you go. This is the four pager

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

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

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

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

Thanks

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 7, 2020 at 1:41:34 PM EST
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:41 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

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

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs
Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:38 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Anna and I

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:38 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

(b)(5)
From: McSeveney, Megan
Sent: Friday, February 07, 2020 1:36 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

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

(b)(5)
From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 7, 2020 at 1:03:54 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Leissa, Brad G <Brad.Leissa@fda.hhs.gov>, Farley, John <John.Farley@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

Laura M. Caliguiri
Associate Commissioner, Office of External Affairs
Office of External Affairs
U.S. Food and Drug Administration
Office 301-796-8546

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 7, 2020 1:01 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2
From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 07, 2020 1:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

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

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

Here you go.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Friday, February 7, 2020 12:46 PM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: NEED 3 COV TPs asap for Dr. Hahn for HHS presser at 2

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

(b)(5)

Need ASAP. Thanks.

Sent from my iPhone

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

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

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

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

Need ASAP. Thanks.

Sent from my iPhone
Unfortunately, we need this asap

Thank you in advance
Hi – don’t send to Commish yet – CDRH tweaking – 
Will send in a few
FYI- today’s ASPR Senior Leader Brief for nCoV attached.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: __________(b)(6)_________

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

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

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

Source: HHS, CDC

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

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

Global Case Counts
- Total global confirmed cases = 31,479
- Total global confirmed deaths = 638
- New Cases (~24 hrs.) = 3,204
- Countries with cases = 28

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

Russell Zablan
Interagency Information Liaison/RFI Lead
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
**Desk:** 404-253-2264
**Cell:** [___ (b)(6) ___]
**Email:** russell.zablan@fda.hhs.gov
IMG Planning Section email:
2019-nCoVFDAIMGPlanning@fda.hhs.gov
Subject: nCoV Daily
Attachments: nCoV Agenda_Jan31.docx
Location: ***UPDATED LOCATION*** EEOB Room 374 SMS Large
Start: 1/31/2020 9:00:00 AM
End: 1/31/2020 10:30:00 AM
Show Time As: Tentative
Recurrence: (none)

Dear Colleagues,

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

Please use the WAVES link to register for attendance.

Best Regards,

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

UNCLASSIFIED // FOR OFFICIAL USE ONLY

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

Source: HHS, CDC

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

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

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

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

For more details, please see attached HHS SLB for Novel Coronavirus which includes the 09Feb20 CDC SITREP for Novel Coronavirus.
As Deaths Mount, China Tries to Speed Up Coronavirus Testing


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

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

Subject: nCoV Daily

Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30_agenda.docx

Location: Updated Location - WHSR JFK

Start: 2/17/2020 9:00:00 AM
End: 2/17/2020 10:30:00 AM
Show Time As: Tentative
To avoid unnecessary confusion, I will send out invites for individual meetings as they are needed and cancel this series.

Best,

Phil
Dear Colleagues,

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

Please use the WAVES link to register for attendance.

Best Regards,

Phil
Dear Colleagues,

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

Please use the WAVES link to register for attendance.

Best Regards,

Phil
Subject: nCoV Daily
Attachments: nCoV DC Options Paper.29 Jan_FINAL.docx; nCoV Jan 30_agenda.docx
Location: Updated Location - WHSR JFK
Start: 2/17/2020 9:00:00 AM
End: 2/17/2020 10:30:00 AM
Show Time As: Tentative
Recurrence: (none)

Dear Colleagues,

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

Best,

Phil
Dear Colleagues,

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Please use the WAVES link to register for attendance.

Best Regards,

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

Hi all - no edits from mg

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

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cell: (b)(6)
Megan.McSeveney@fda.hhs.gov
From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Monday, February 10, 2020 9:50 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

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

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

Karas, please share with Stacy. Adding her here.

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

Thanks, Anna.

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

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

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

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

Internal confidential

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

Internal, confidential, pre-decisional

Hi Anna and Keagan-

(b)(5)

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

Thanks!

Karas
Subject: nCoV Daily
Attachments: nCoV DC Options Paper 29 Jan_FINAL.docx; nCoV Jan 30 Agenda.docx; Canceled: nCoV Daily; Canceled: WCoV
Location: Updated Location
Start: 1/30/2020 9:00:00 AM
End: 1/30/2020 10:30:00 AM
Show Time As: Tentative

Dear Colleagues,

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

Best,

Phil
Dear Colleagues,

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

Best,

Phil
No comments from OCC. thanks

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

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

Thanks

Bill

Sent from my iPhone

Begin forwarded message:

From: "Wilson, John Mark M. EOP/NSC" (b)(6)
Date: February 10, 2020 at 9:59:57 AM EST
To: "Murphy, Ryan (OS/ASPA)" <Ryan.Murphy1@hhs.gov>, "Hall, Bill (HHS/ASPA)" <bill.hall@hhs.gov>, "Michael, Gretchen (OS/ASPR/OEA)" <Gretchen.Michael@hhs.gov>, "BrownC4! (bl(G) .J<BrownC4l (b)(6) "Ortagus, Morgan D" <bj(6)"Farah, Alyssa A SES (USA)" <b(6)"Hoffman, Jonathan R SES OSD OSD (USA)"
Cc: "Ullyot, John L. EOP/NSC" <bj(6); "Martin, Michael E. EOP/NSC"
Subject: NCOV Fact Sheet

Colleagues

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

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

Thanks

John Mark Wilson  
Office of Strategic Communications  
National Security Council  
Office: 202-456-9275  
Cell: (b)(6)
I know you’re in a meeting so highlighting for you

---

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

Megan McSeveney

Press Officer

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

---

Bruce Ross, MA, MPH

Director, (Acting)

Office of Global Operations
Office of Global Policy and Strategy
Hi all – we have a very short turnaround from NSC via HHS. Each HHS OpDiv is being asked to share bullets about our efforts during this coronavirus outbreak to date. Below and attached as FDABULLETSFORNSC is an initial draft. I need any edits/additions back by 12:30. I am sending this for concurrent review given the tight deadline. Thank you all!
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NSC wants to pull together a fact sheet that summarizes key actions that the USG has taken to date as part of the coronavirus response. Can you all please send me by 12:30 pm today, a bullet list of key actions your agency has taken?

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Bill

Sent from my iPhone

Begin forwarded message:

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

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

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

Thanks

John Mark Wilson  
Office of Strategic Communications  
National Security Council  

Office: 202-456-9275  
Cell: (b)(6)
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/10/2020 12:43:37 PM
To: Mair, Michael [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/CN=Recipients/CN=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]; Courtney, Brooke [Brooke.Courtney@fda.hhs.gov]
Subject: For Action: Review RPD Strategy by COB Today
Attachments: USG Roadmap to Extend RPD Supply _Draft 021020.docx
Importance: High

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

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

Good morning all,

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

Thanks,
Brittney

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

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

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

Laura

Laura K winn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov.gov
Desk: (b)(6)
Cell: (b)(6)
Hi,

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

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

Many thanks for your continued support. -Michael
Dear Colleagues,

FDA-OSJ-FOIA-2020-3541 _00006906

Subject: WCoV

Attachments: Phases of USG nCoV ResponseCOORD.docx

Location: EEOB Room 445 Please submit WAVES for each meeting

Start: 2/11/2020 10:30:00 AM
End: 2/11/2020 12:00:00 PM
Show Time As: Tentative
Importance: High
The WHTF has directed the development of a document that will be developed by the WHTF over the next 36 hours. The document will be discussed by the WHTF during their in-person meeting on Wednesday. SAP Ruggiero will convene a WCoV PCC tomorrow to develop the aforementioned document. You will find attached a first draft of the framework. The expectation is that D/A will come to the meeting prepared to discuss the overarching framework as well as to provide (in writing) the contributions, roles and responsibilities of their D/A.

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

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

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

Please use the WAVES link to register for attendance.

Best Regards,

Phil
From: Rath, Prakash (FDA) [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=91BC5673D6C416E87A453F8B9527CC0-PRAKASH.RAT]
Sent: 2/10/2020 9:04:23 PM
Subject: RE: China Inspections Tear Sheet--AMA

Thank you, Megan!

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

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

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-4514/Cel_ _____ .(b)(G) ·-·-·-· I
Megan.McSeveney@fda.hhs.gov

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

Adding Mark
Hi Karas – (b)(5) Thank you!

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

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

Any updates on this?

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

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

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

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, February 10, 2020 10:41 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA
Hi all - no edits from me. I am still catching up on email after a weekend away so apologies if I am being duplicative but, the JIC knows about this request and we will be checking with IMG to make sure the information is up to date.

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-4514/Cel: 240-402-4515
Megan.McSeveney@fda.hhs.gov

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

Attached here. Stacy

Any edits are appreciated. Thanks!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 10, 2020 9:45 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
CC: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Karas, please share with Stacy. Adding her here.

---

Thanks, Anna.

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

Megan. Asking in case ASL asks for another update. Thanks!

---

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

See attached.

Internal confidential

---

Hi Anna and Keagan-
(b)(5)

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

Thanks!
Karas
Thanks Laura.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation
Center for Devices and Radiological Health (CDRH)
Office of Strategic Partnerships and Technology Innovation (OST)
U.S. Food and Drug Administration
WO68, Room 5410
Tel: 301-796-6937
Cell (b)(6)
Suzanne.Schwartz@fda.hhs.gov

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

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

Suzanne, et al-

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

Laura

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

Market Capacity
In the span of less than 2 weeks, since late January to 5 February 2020, the market’s ability to produce personal protective equipment (PPE) to meet demand has been drastically eroded. There is currently an extreme level of demand that has overwhelmed the supply capabilities of the PPE market. However, though the production capacity has been overwhelmed, preliminary assessments have determined that the market collapse is primarily due to aggressive demand. Currently, the specific item in greatest demand is surgical masks. It is anticipated that additional PPE items like gloves, gowns and goggles will experience market pressures.

- The most significant obstacle facing the market today is ensuring surgical masks are sourced and allocated to frontline health workers and other responders in affected countries and those countries most vulnerable to the spread of 2019 nCoV.
- Focusing on surgical masks because of the immediate demand and market pressures, the WHO is estimating that global frontline health emergency responders will require approximately 7% - 10% of the markets’ capacity to effectively stop the outbreak.
- The greatest concentration of production for surgical masks is in China. Approximately 50% of the surgical masks capacity is in China. Additional countries include India, Thailand, Malaysia, Japan, Mexico, US, Korea and several European countries.
- Several manufacturers and wholesalers mentioned that production for surgical masks and other PPE items have been significantly shifted to Mexico with Mexico experiencing 100% utilization rates and will for the next 4 to 6 months. Across the market, backlog is running at similar timeframes of 4 to 6 months.
- Finally, any increase in production capacity is estimated to be between 20% and 40% with a ramp-up period of 3 to 4 months.

**Logistics**

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

---

From: Ryan Morhard <Ryan.Morhard@weforum.org>
Sent: Monday, February 10, 2020 10:29 AM
Cc: GRIFFIN, Michael <griffinm@who.int>; Arnaud Bernaert <Arnaud.Bernaert@weforum.org>
Subject: Attached - PSCN PPE Market Assessment Report

Dear PSCN colleagues,

Please find the market assessment report attached. And thank you to those stakeholders within PSCN who’s input has served as a basis for the findings outlined in the report.
Looking forward to our call tomorrow. As a group, I hope we can use that call to consider how, together, we might alleviate some of the pressures and achieve a more optimal response overall.

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

Ryan

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

Ryan.Morhard@weforum.org

(b)(6)
Attached is the ASPR Senior Leadership Brief and below is information from the HHS International SPOTREP: Novel Coronavirus, Wuhan, China

UNCLASSIFIED // FOR OFFICIAL USE ONLY

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

Source: HHS

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

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

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

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

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
From: Scherf, Uwe /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP

(FYDIBOHF23SPDLT/CN=RECIPIENTS/CN=B184B713FC4D4EDC84D1AE0D78AAFC7-UXS)

Sent: 2/11/2020 11:47:04 AM

To: McSeveney, Megan /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT/cn=Recipients/cn=0d4b7fc0cfe46c7b1be4d4f24d07-Megan.McSev); CDER-OPS

(FYDIBOHF23SPDLT/cn=Recipients/cn=e4aa67416e2b4b0b0ea03681b334525-CDER-OPS);

Choe, Lena /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT/cn=Recipients/cn=87e73b7c30d4023b19ad98cc1c1c9186-CHOELE); 2019-nCoV FDA IMG

(FYDIBOHF23SPDLT/cn=Recipients/cn=b1303ad717c4c5b45c63acc50e311f-2019-nCoV F);

Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT/cn=Recipients/cn=859eca0be0694803be6030e97c744a-HINTOND); Kumar, Dinesh

(FYDIBOHF23SPDLT/cn=Recipients/cn=508e6d982bf426cab84531e12cf3d46-Dinesh.Kuma); Raza, Mark

(FYDIBOHF23SPDLT/cn=Recipients/cn=5811a7d77e3e4aa78ff3cc9cbb9f9ee-MRaza); Beers, Donald

(FYDIBOHF23SPDLT/cn=Recipients/cn=d079bf15a0174bb94687d6718ca4c42-Donald.Beer); Anderson, Erika

(FYDIBOHF23SPDLT/cn=Recipients/cn=9860962b9946aefb25aba1e3573dfde-Amanders); Abram, Anna

(FYDIBOHF23SPDLT/cn=Recipients/cn=fb776089138423a7c9086fcbba1a3b-Anna.Abram); Lenihan, Keagan

(FYDIBOHF23SPDLT/cn=Recipients/cn=ee73200e8c34b966b521b0129d72-Keagan.Len); Sadove, Elizabeth

(FYDIBOHF23SPDLT/cn=Recipients/cn=fad4c67200649b36a2b40b2-SADOVE); Sapsford, Kim E

(FYDIBOHF23SPDLT/cn=Recipients/cn=564aa540b77d455b922015ece2101829-KIS); Ross, Jennifer

(FYDIBOHF23SPDLT/cn=Recipients/cn=44ae562ea1d840a3ca172d0cc23f368-RossJ)

CC: Rebello, Heidi /o=ExchangeLabs/ou=Exchange Administrative Group

(FYDIBOHF23SPDLT/cn=Recipients/cn=283a4c193ca94979e063e34a2ca0b-Heidi.Rebel); McNeill, Lorrie

(FYDIBOHF23SPDLT/cn=Recipients/cn=77b0b352c92b4851bf0c330f53e0d9-McNeill); Lowe, Toby A

(FYDIBOHF23SPDLT/cn=Recipients/cn=58547e0b759243106bca179f4d0b-TAL)

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

Attachments: ASPR News Release 2019-nCoV vaccine1_v7RB for HHS clearance.docxFDA.docx

Megan,

A couple of comments from the diagnostics perspective. Uwe

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

Director, Division of Microbiology Devices

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

CDRH | Food and Drug Administration
White Oak, Bldg 66 Rm 4516 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-5456
usw.scherf@fda.hhs.gov

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

https://www.research.net/s/cdrhcUSTOMER SERVICE?ID=1930&S=E
Hi all – please see the attached PR from ASPR. Asking for concurrent clearance given the short turnaround and the reference to (b)(5). CDRH -copying Heather Agler through the IMG, as well as Uwe and Kim since this references the EUA. Also, cc'ing Jennifer Ross from OCET and Toby Lowe (CDRH) given reference to EUA.

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

V/R,

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

From: OS HHSPress (HHS/ASPA) <HHSPress@hhs.gov>
Sent: Tuesday, February 11, 2020 9:02 AM
To: OS - ASPA - Clearance <OS.ASPA-Clearance@hhs.gov>; OS - ASPA - Public Health Clearance <OS.ASPA-PublicHealthClearance@hhs.gov>
Cc: Michael, Gretchen (OS/ASPR/OEA) <Gretchen.Michael@hhs.gov>; Kane, Eileen (OS/ASPR/OEA) <Eileen.Kane@hhs.gov>; Walz, Christopher (OS/ASPR/OEA) <Christopher.Walz@hhs.gov>
Subject: CLEARANCE_0130: ASPR: HHS, [Company] join forces on coronavirus vaccine

Close-Hold

Agency/Office: ASPR

Subject (or headline): 2019-nCoV vaccine development

Materials: Press release

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

Planned release date: Wednesday, February 12

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

V/R,
Naweed Lemar
U.S. Department of Health and Human Services
Direct: 202-260-6962
Mobile: (b)(6)
Email: naweed.flemar@hhs.gov
From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 12:32 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Yates, Thomas <Thomas.Yates@fda.hhs.gov>
Subject: RE: 2 PCCs tomorrow, 11 FEB

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

---

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

Dear Anna,

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

Best Regards,

Peter

---

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

Hi.

There are two PCCs tomorrow, one from 10:30 AM – 12:00 PM and a second from 3:00 – 4:00 PM.
See description/purpose of meeting below from NSC.

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

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

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

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization. FYSA, you will also see an invite for another PCC tomorrow from 1500-1600 in case it is needed as well as an invite for Wednesday morning.
From: Gross, Karas /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0B6D3DC4EE4B4150D86EC634C536453B6-KARA.GROSS
Sent: 2/11/2020 4:08:18 PM
To: McSeveney, Megan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=04d4b7fc0cfed46c7b1bfcddd41f240d7-Megan.McSev; Abram, Anna /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=fb77660891384232a7cd9086fcb1a3b-Anna.Abram; Anderson, Erika /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=98606928b9a64edf25aba1e3573dfde-Eranders; Raza, Mark /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=5811a7d72ee34aa78ff3c8ccbb59f92ee-MRaza; Rath, Prakash (FDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat; Mair, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai; Lenihan, Keagan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=ee7320ee8c184d66fd521b0105d17d2-Keagan.Leni
CC: Aguilar, Paul /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=9f4e6056acc4bc98f6db07bb0548dc8-Paul.Aguila; Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=85feca0be894803be6303e97c74adb-HINTOND; Amin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=cb3764b7438648833c22881a06fc6af-Heidi.Rebello; Kumar, Dinesh /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=283ace193ca949799ef063e34a2cfa0b-Heidi.Rebello; Beers, Donald /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=recipients/cn=d079bf15a01744bd94687d6718ca4c-Donald.Beers
Subject: RE: FOR ANNA - EDITS RE: China Inspections Tear Sheet--AMA

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

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

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

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

Megan McSeveney
Press Officer

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

FDA-OSJ-FOIA-2020-3541_00000497
From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 1:58 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Agulilar@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Reubello, Heidi <Heidi.Reubello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA
Importance: High

An update.

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

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

Caught a typo – otherwise OK here. See attached.

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

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

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

Hi Karas,

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

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

(b)(5)

Erika

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 10:03 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA)
   <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>
   Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise
   <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
   Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

Thanks, Mark!

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

(b)(5)
From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 8:13 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: EDITS RE: China Inspections Tear Sheet--AMA

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

---

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 6:54 AM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: EDITS RE: China Inspections Tear Sheet--AMA

Morning! Please see edits from Prakash and me - attached are tracked and non-tracked versions. Mark– wanted to flag that we have highlighted four bullets in this tracked version that have either been added or edited to hopefully help with your review.

While this is still a bit long, `[this is a bar]` both Prakash and I are happy to quickly make any edits this morning. Thank you!

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

---

From: Gross, Karas <Karas.Gross@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 6:30 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Thanks, Megan!
Mark, do you need to review for Stacy? (b)(5)

Thanks!

(b)(5)

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

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

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

From: McSeveney, Megan
Sent: Monday, February 10, 2020 7:43 PM
To: Gross, Karas <Karas.Gross@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

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

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-4514/Cell (b)(6) __ ______
Megan.McSeveney@fda.hhs.gov
Thanks for tracking this down. Can you please make the appropriate edits based on these comments. Thanks!

Adding Mark
Thank you!

Hi Karas--

Thank you!

Megan McSeveney
Press Officer

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

(b)(5)
Any updates on this?

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

I will send a note to CDER__along with Prakash unless others would like to do that. Thank you!

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-4514/Cele(6)___
Megan.McSeveney@fda.hhs.gov

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, February 10, 2020 10:41 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: China Inspections Tear Sheet--AMA

Hi--

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

Hi all - no edits from me! I am still catching up on email after a weekend away so apologies if I am being
duplicative but, the JIC knows about this request and we will be checking with IMG to make sure the information is up to date.

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

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

Attached here. Stacy, Any edits are appreciated. Thanks!

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

Karas, please share with Stacy. Adding her here.

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

Thanks, Anna.

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

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

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

See attached.

Internal confidential

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

Internal, confidential, pre-decisional

Hi Anna and Keagan-

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

Thanks!
Karas
Thanks Larry.

Denise

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

February 11, 2020 8.53am EST

Authors

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

2. Andrew Natsios
   Director, Scowcroft Institute of International Affairs and Executive Professor, Texas A&M University

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

[You’re smart and curious about the world. So are The Conversation’s authors and editors. You can read us daily by subscribing to our newsletter.]
The silent threat of the coronavirus: America’s dependence on Chinese pharmaceuticals

February 11, 2020 8.53am EST

Authors
1. Christine Crudo Blackburn
   Postdoctoral Research Fellow, Scowcroft Institute of International Affairs, Bush School of Government and Public Service, Texas A&M University
2. Andrew Natsios
   Director, Scowcroft Institute of International Affairs and Executive Professor, Texas A&M University
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When a disease reaches epidemic levels, the first obligation for leaders in any country is to protect their own people. As this current crisis progresses, there may come a point when political leaders in China will face decisions on whether to prohibit the export of pharmaceuticals, medical devices and other vital medical components in order to treat or protect their own people. Such acts would be the logical outcome of an escalating situation. For the 2009 H1N1 pandemic response, for example, the U.S. was pushed to the back of the queue for vaccine deliveries even though we had existing contracts with a major vaccine manufacturer located in another country. Those vaccine deliveries were delayed.
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[You’re smart and curious about the world. So are The Conversation’s authors and editors. You can read us daily by subscribing to our newsletter.]
Subject: WCoV
Attachments: Phases of USG nCoV Response_11Feb_Dist.docx; NCoV Control-Containment-Mitigation DRAFT 2.docx
Location: West Wing WHSR JFK ***Please submit WAVES ASAP**
Start: 2/12/2020 8:30:00 AM
End: 2/12/2020 10:00:00 AM
Show Time As: Tentative
Recurrence: (none)

Dear Colleagues,

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

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

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

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

Please use the WAVES link to register for attendance.

Best Regards,

Phil
From: Ferro, Phil J. EOP/NSC
Sent: 2/11/2020 9:23:41 PM
To: Ferro, Phil J. EOP/NSC

Subject: EOP/NSC

[Message Content]

[PDF Content]
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Please use the WAVES link to register for attendance.

Best Regards,

Phil
Hi Denise,

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

Thank you,
Prakash

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

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

- **FDA/CDER Drug Shortage Staff (DSS) has an established reporting process for medical drug product shortages.** Manufacturers are required to report potential drug shortages to the FDA, and are required to report the reasons for shortages and the expected duration of shortages on the FDA website. Title X of the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012, signed on July 9th, lists the mandatory reporting requirements for manufacturers. Please refer to: [https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages](https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages)

- **CDER/DSS has established direct communications and provided a direct point of contact at DSS for manufacturers of human medical drug products regarding impacts to API and/or finished drug product from the COVID-19 event.** Regulatory representatives for approved medical drug products for the US market have been contacted and directly requested to provide supply chain status for their human medical drug products supply affected by facilities that could be impacted by the COVID-19 event in China. In particular, API and/or finished dosage forms, current or future production of API and/or finished drug products and any projected impact to drug product supply for the US market.

- **CDER/DSS participates in a monthly Global Regulatory Shortage working group meeting of regulators at EMA (European Medicines Agency), MHRA (Medicines & Healthcare products Regulatory Agency: UK), TGA (Therapeutic Goods Administration: Australia), and Health Canada.** Respective regulatory authorities are also monitoring impact of COVID-19 to drug product supply.

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

FDA-OSJI-FOIA-2020-3541_00003851
Good morning,

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

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

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

Many thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) brooke.courtney@fda.hhs.gov
February 12, 2020
The epidemic spread of coronavirus in China — along with community transmission in Singapore, Hong Kong, and Japan — sharply increase the chance that we endure pandemic spread. Worse still, the novel coronavirus may become endemic. It could take a new position as a more sinister member of the seasonal pathogens that circulate each year and infect humans.

The next month is critical. We must prepare for the prospect that the virus evaded our border protections and was already introduced into the U.S. in late December or early January — when it first appears to have become epidemic in
China’s Hubei province. Those index cases could have seeded community spread, and eventually, outbreaks could emerge in America. We have the capacity to contain small outbreaks. But we need to be vigilant and ready.

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

Full Testimony

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

Securing alternative supply in the setting of a crisis takes time. But here are steps U.S. regulators can take in the near term, working with Congress and other partners, to lessen the potential impact of supply disruptions on Americans by identifying vulnerabilities and bringing substitute supply online. There are also longer-term policy steps that we could take to reduce the vulnerabilities created by these choke points in the supply of critical public health goods. I want to address in greater detail these issues as they relate to drugs and production in China. About 40 percent of generic drugs sold in the U.S. have only a single manufacturer. A significant supply chain disruption could cause shortages for some of many of these products.

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

While much of the fill finishing work (the actual formulation of finished drug capsules and tablets)
is done outside China (and often in India) the starting and intermediate chemicals are often sourced in China. Moreover, the U.S. generic drug industry can no longer produce certain critical medicines such as penicillin and doxycycline without these chemical components.

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

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

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

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

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

How can we take steps to try and address some of these significant challenges?

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

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

In the near term, FDA can issue a solicitation for such information. U.S. officials should already have some awareness of the key components that are manufactured in China, and in the Hubei Province particular. But in the longer term, we need a more systematic process for collecting this
information. This is where Congress can help, by giving the FDA authority to look not only at the supply of finished products but to also identify circumstances where key components may have only a single source across an entire category of products. This may take the form of a requirement that manufacturers develop risk management plans that explicitly surface critical supply chain choke points. In turn, we could require companies to take steps to identify alternative sources in the event of a major disruption. It isn’t just supply disruptions we need to be fearful of. In the setting of a public health crisis in a country that hosts the manufacture of critical components, a government may seek to withhold supply or even nationalize key facilities if the components are essential to their own relief efforts. A nation could seek to satisfy its in country needs before they ship outside their borders. Such a circumstance arose with respect to the manufacture of flu vaccine after the H1N1 pandemic.

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

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

As a consequence, some new drug programs could be delayed as innovators are forced to change clinical trial enrollment plans, amend protocols, or shift certain critical development activities to other CROs located in other regions. This could delay regulatory filings on new drugs. We also must address potential device shortages. Medical devices operate under a different framework than drugs. It may be harder to identify and mitigate potential shortages. We should adopt the same practices we’ve implemented for drugs – which requires manufacturers to give FDA early notification of potential shortage situations. More than a year ago, FDA first put forward such a proposal. That proposal was incorporated into the President’s current budget. Finally, we should also contemplate for medical devices a similar framework to the one I believe we need for drugs. It would require manufacturers to report to FDA when there is a key component that is sole sourced and where alternate supply cannot be easily obtained.
While we hope no shortages will result from the tragic epidemic, given the concentration of production work in Wuhan, the risk is real. Those risks can be reduced through careful planning. In the long run, there are structural changes we can make to reduce these risks for when next global crisis arises. It starts with shifting our emphasis. We’ve been focused on the risk that finished goods can fall into shortage owing to a supply disruption. In a world where the manufacture of components and source material has become highly centralized around a small number of regions and facilities, we need to pay equal attention to identifying these other choke points and taking steps to make sure that critical production doesn’t hinge on a single location.
Yes - CDRH held a call with CDC Monday to discuss (b)(5)

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

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

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

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

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

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 2:54 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: supply chain/coronavirus
We need an answer here to the questions the Hill is raising. Can IMG get back to us?

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

Begin forwarded message:

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

Many thanks!

Virginia Heppner McMillin
Special Assistant to the President
Office of Legislative Affairs

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

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

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

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

Virginia McMillin
Special Assistant to the President
Office of Legislative Affairs

On Feb 12, 2020, at 1:42 PM, Kuskowski, Jennifer (McConnell) wrote:
Hey there – can you provide details on how HHS and specifically FDA are responding to concerns about the potential for (b)(5) Appreciate any and all information you can share on this issue. I’d anticipate it coming up at Azar’s budget hearing tomorrow, and perhaps in other venues as members continue to discuss the ramifications of the Coronavirus.

Thanks!
Jen
I am sharing this first take at a statement outlining our response efforts to make sure it strikes the right tone as well as captures the topics of importance. If you think we are on the right path, please send me any initial comments and I will take it through the IMG. I’ll send you a final draft before it goes to the Commissioner and then HHS. Thank you.
Some initial thoughts here and in the document. Will review more as it moves forward.

(b)(5)
From: Jones, Estella /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=99A7F2B2D73D42E18320F066766880C1-ESTELLA.JON
Sent: 2/12/2020 11:20:49 PM
To: Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND
Subject: RE: Support to combat 2019-nCoV

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

(b)(5)

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

(b)(5)

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

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


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

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

Thanks Estella, we will.

Best,
Hi Daniela,

We think that this outbreak will get more attention and possibly funding in the future but right now we don't have funds to address it. I will keep you posted on any new developments. Tracy is out of the office right now but I will make sure that she is aware.

Best,

Estella

Dear Estella,

I would like your take on the current Corona virus crisis. As you know, a new betacoronavirus, 2019-nCoV, has emerged discovered in Wuhan, Hubei province of China and it appears to spread from human to human through aerosols. The virus has so far infected at least 2,800 people in China and killed at least 82. Chinese officials are reporting sustained person-to person spread is occurring in China. World Health Organization is closely monitoring the situation as China has quarantined 41 million people in 13 cities to contain the disease. As of January 27th 2020, 16 countries including United States (5 cases) have confirmed 2019-nCoV cases. Taking the current scenario into consideration, I believe we can expect a rapid surge in vaccines and therapeutics aimed at controlling the new pathogen. I wanted to know your thoughts on immediately committing resources to develop animal models the lab to help with the development and regulation of the therapeutics and vaccines that will come to the Agency. Our lab has recently developed mouse models for emerging and re-emerging infectious.diseases.including Zika and Ebola virus and are currently characterizing our new mouse model for Dengue virus.
Please let us know, if these align with the priorities of the Office of Counter terrorism and Emerging Threats and if funding might be available to support these projects. Please don’t hesitate to contact us if you think we can help with anything to combat this new public health crisis.

Thanks,

Daniela Verthelyi
Dr. Dixon,

We appreciate your leadership and support.

Thanks

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

-----Original Message-----
From: Stacey.A.Dixon [Redacted]
Sent: Wednesday, February 12, 2020 9:50 AM
To: Ernest Smiley [Redacted]; 
 Alexander.Berge [Redacted]; Denise.Hinton@fda.hhs.gov
CC: DDS staff [Redacted]
Subject: RE: FDA and NGA Collaboration

Classification: UNCLASSIFIED

Ernest,
Thank you for the forward.

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

Sincerely,
Stacey

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

Dr. Dixon,

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

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

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

Thanks for your leadership and dedication

ERNEST L. SMILEY, MS, MBA, CISM, CGEIT, CRISC, CPM
CHIEF DATA SCIENTIST
Kingdom Capital

(b)(6)

www.KingdomCapital.com

Classification: UNCLASSIFIED
From: Caliguiri, Laura /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIHOBF23SPDLT)/CN=RECIPIENTS/CN=AA086F226C9346C49E99932D68AC62E-LAURA.CALIGR)

Sent: 2/13/2020 2:17:12 PM

To: McSeveney, Megan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=0d4b7fc0c6ed4c67b1bfcddd41f240d7-Megan.McSev); Abram, Anna /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=fbe77660891384232a7cd908efcba1a3b-Anna.Abram); Gross, Karas /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=06d3dc4ee4b415d86ec634c536453b6-Kara.Gross); Rath, Prakash (FDA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=91bc5673db6c416e87a453f8b957cc0-Prakash.Rath); Rebello, Heidi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=283ace193ca949799ef063f34a2cfa0b-Heidi.Rebello); Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=85feca0be694803be6030e97c7b4adb-HINTON); Lenihan, Keagan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=ee7320ee8c184267d521b0105d17d2-Keagan.Lenihan); Janik, Heather /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=117bc4d27d7b47ddbebee5f6ebf7f3-heather.Jan); Anderson, Erika /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=98606928b9a64edfb25aba1e3573fdef-Anderson); Pennington, Caitlin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=6d2ds63dd0e741d3afe78f9ae75349a0-PENNINGTONC); Tantillo, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=43045befee8f46fa99da0c3d47272a1c-Andrew.Tant); Black, Jennifer /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=af8a19f3672942293a7c1b2d1498059-Jennifer.BI); Barber, Daniel /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=0a326d10d45483f843d99d59bf1e5d-Daniel.Barb); Walsh, Sandy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=615034e7884f28b9ef6cbbf2514e-Sandy.Walsh); Hebert, Angelique A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=9aa09f3b428a045f88eb392c68a27cf-Angelique.H); Finnen, April /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=43d74b30bb14d29184b0d9081e6e19bf-April.Finnen)

CC: Anderson, Erika /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=98606928b9a64edfb25aba1e3573fdef-Anderson); Pennington, Caitlin /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=6d2ds63dd0e741d3afe78f9ae75349a0-PENNINGTONC); Tantillo, Andrew /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=43045befee8f46fa99da0c3d47272a1c-Andrew.Tant); Black, Jennifer /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=af8a19f3672942293a7c1b2d1498059-Jennifer.BI); Barber, Daniel /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=0a326d10d45483f843d99d59bf1e5d-Daniel.Barb); Walsh, Sandy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=615034e7884f28b9ef6cbbf2514e-Sandy.Walsh); Hebert, Angelique A. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=9aa09f3b428a045f88eb392c68a27cf-Angelique.H); Finnen, April /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIHOBF23SPDLT)/cn=recipients/cn=43d74b30bb14d29184b0d9081e6e19bf-April.Finnen)

Subject: For Clearance CDER FAQs and Inside FDA for employees

All
Below please find the below internal and external docs for your clearance. They have cleared the IMG, including OCC. Please let me know if there are edits ASAP today.
Thank you very much.
Laura

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

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

DRAFT CDER FAQs page (fda.gov)
(b)(5)
(b)(5)
Hi all --

(b)(5)

(b)(5)

Thank you!

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

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

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

Courtney, I will look at this shortly, but you (OCET) should close the loop with ASPR. Just make sure Keagan and I have the finals.
From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, February 13, 2020 2:13 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing
Importance: High

Anna and Keagan,

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

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

Thanks,
Brooke

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, February 13, 2020 1:33 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Can I see the slides please?

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 13, 2020 12:53 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing
I haven’t heard anything further from the ASPR team so let’s just proceed based on what we know and loop back with them.

---

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, February 13, 2020 10:52 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Hi Anna,

Thank you for the input.

Thanks,
Brooke

---

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 13, 2020 10:47 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Plus Keagan

---

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, February 13, 2020 8:42 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: FW: Urgent: Information request for ASPR White House Briefing
Importance: High

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

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

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

Thanks!
Brooke

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

From: Courtney, Brooke
Sent: Wednesday, February 12, 2020 6:54 AM
To: Jackson, LeeAnne <LeeAnne.Jackson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Brad Leissa (brad.leissa@fda.hhs.gov) <brad.leissa@fda.hhs.gov>; Roberts, Rosemary (Rosemary.Roberts@fda.hhs.gov) <Rosemary.Roberts@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Hornung, Matthew <Matthew.Hornung@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hashemi, Sema <Sema.Hashemi@fda.hhs.gov>; Gabriel, Celia <Celia.Gabriel@fda.hhs.gov>; Christensen, Lane <Lane.Christensen@fda.hhs.gov>; 'Sutton, William' <William.Sutton@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Rotstein, David <David.Rotstein@fda.hhs.gov>; Glover, Mark <Mark.Glover@fda.hhs.gov>; Ngan, Kelly (Kelly.Ngan@fda.hhs.gov) <KELLY.NGAN@FDA.HHS.GOV>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ellis, Patricia <Patricia.Ellis@fda.hhs.gov>; Block, Frank <Frank.Block@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; 2019-nCoV FDA IMG Operations <2019-nCoV@FDA.IMG.Operations@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>

Subject: Urgent: Information request for ASPR White House Briefing
Importance: High

Good morning,

I realize many of you have already received the attached request from HHS/ASPR to review and add (b)(5) for a White House briefing on Friday (this is the same request we mentioned during yesterday afternoon’s IMG and AEG meetings). In addition to FDA, other HHS partners (CDC, BARDA, SNS, and ASPR/Division of Critical Infrastructure Protection (CIP)) have been asked to contribute (b)(5) information.
The deadline for FDA to return edits to ASPR is 2:00 pm today. Ideally, we’d like to send a single FDA response back to ASPR, so if you could send me your edits/comments by **12:00 today** that would be super so we can give leadership the opportunity to review before 2:00 if needed since this issue is a very high priority. CDRH, we’ve seen your great comments about \( (b)(5) \) and will work to incorporate those as well.

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

Many thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) \( \text{(b)(6)} \) (cell)
brooke.courtney@fda.hhs.gov
We will use this time to prep for the Friday (1/14) briefings on supply chain during the coronavirus outbreak. Questions that we will prepare for will be based on what was asked during the calls and briefings over the last two days.

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

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Sent: 2/13/2020 4:04:33 PM
To: Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ee634c556453b-Kara.Gross]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43045bf8ee846faa9da0c3d4772a1c-Andrew.Tant]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Pennington, Caitlin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONC]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ed1654e65992a9a5bbe59630-SCHIPPERJ]; McSeveney, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0d4bf76c0fe4d6c7b1bfcdd41f2407d7-Megan.McSev]; Howard, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67c6d6fa26326-Megan.Howard]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4add-HINTOND]; Shirley, Mayo [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]

Subject: Prep for Friday Congressional Phone Briefing on Supply Chain
Attachments: Draft Statement AA.docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA.docx
Location: RADM Hinton's office or WebEx

Start: 2/13/2020 4:15:00 PM
End: 2/13/2020 4:45:00 PM
Show Time As: Tentative

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Sent: 2/13/2020 4:04:33 PM
To: Black, Jennifer [o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8e19f3672492293a7c1b2d1498059-Jennifer.Bl]; Abram, Anna [Anna.Abram@fda.hhs.gov]; Gross, Karas [Karas.Gross@fda.hhs.gov]; Tantillo, Andrew [Andrew.Tantillo@fda.hhs.gov]; Aguilera, Paul [Paul.Aguilera@fda.hhs.gov]; Pennington, Caitlin [Caitlin.Pennington@fda.hhs.gov]; Schipper, Jodi [Jodi.schipper@fda.hhs.gov]; McSeveney, Megan [Megan.McSeveney@fda.hhs.gov]; Howard, Megan [Megan.Howard@fda.hhs.gov]; Hinton, Denise [Denise.Hinton@fda.hhs.gov]; Shirley, Mayo [Mayo.Shirley@fda.hhs.gov]; Rath, Prakash (FDA) [Prakash.Rath@fda.hhs.gov]; Patel, Paras M [Paras.Patel@fda.hhs.gov]; Jensen, Valerie E [Valerie.Jensen@fda.hhs.gov]; Agler, Heather L [Heather.Agler@fda.hhs.gov]

Subject: Prep for Friday Congressional Phone Briefing on Supply Chain
Attachments: Draft Statement AA.docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA.docx
Location: RADM Hinton's office or WebEx

Start: 2/13/2020 4:15:00 PM
End: 2/13/2020 4:45:00 PM
Show Time As: Busy

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Sent: 2/13/2020 4:37:44 PM

To: Aguilar, Paul
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=9f4e6056accc4bc98fdd07bb0548dc86-Paul.Aguila]; Pennington, Caitlin
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=6d2d563dd0e741d3afe78f94e75349a0-PENNINGTONCJ]; Schipper, Jodi
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=2373b9ecc6154e65992a9a5fbee59630-SCHIPPERJ]; McSeveney, Megan
[O=ExchangeLabs/OU=Exchange Administrative Group
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[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=905c2a2f4a4c45f1bf9f67c66fa26326-Megan.Howar]; Hinton, Denise
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[O=ExchangeLabs/OU=Exchange Administrative Group
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[O=ExchangeLabs/OU=Exchange Administrative Group
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[O=ExchangeLabs/OU=Exchange Administrative Group
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[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=5a45d66902d87e822c2a7b33f652b-Jennifer.To]; Courtney, Brooke
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Roberts, Rosemary
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=b7838eb9964e4ca1a7d703876d08411b-ROBERTSR]

Subject: From: Black, Jennifer

Sent: Thursday, February 13, 2020 4:28 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew
<Andrew.Tantillo@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Pennington, Caitlin
<Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; McSeveney, Megan
<Megan.McSeveney@fda.hhs.gov>; Howard, Megan <Megan Howard@fda.hhs.gov>; Hinton, Denise
<Denise.Hinton@fda.hhs.gov>; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>; Rath, Prakash (FDA)
<Prakash.Rath@fda.hhs.gov>; Patell, Paras M <Paras Patell@fda.hhs.gov>; Jensen, Valerie E
<Valerie.Jensen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>

Subject: Prep for Friday Congressional Phone Briefing on Supply Chain

Attachments: Draft Statement AA.docx; 021320_CDRHCDERCFSANORA1515AA (003).docx; 2.14.20 Talking Points Member meeting for Denise.docx; nCoR 2-14-20 Talking Points and QnA.docx

Please see the attachments referenced on this call.

From: Black, Jennifer

Sent: Thursday, February 13, 2020 4:28 PM

To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tantillo, Andrew
<Andrew.Tantillo@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Pennington, Caitlin
<Caitlin.Pennington@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; McSeveney, Megan
<Megan.McSeveney@fda.hhs.gov>; Howard, Megan <Megan Howard@fda.hhs.gov>; Hinton, Denise
<Denise.Hinton@fda.hhs.gov>; Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>; Rath, Prakash (FDA)
<Prakash.Rath@fda.hhs.gov>; Patell, Paras M <Paras Patell@fda.hhs.gov>; Jensen, Valerie E
<Valerie.Jensen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Please join this call at 2/13 4:15

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Jennifer R. Black, J.D.
Congressional Affairs Specialist
Office of Legislation
One edit in the attached.\n
Internal confidential

Anna and Keagan,

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

I’m also separately attaching.\n
Thanks,
Brooke

From: Courtney, Brooke  
Sent: Thursday, February 13, 2020 1:37 PM  
To: Lenihan, Keagan; Abram, Anna; Hinton, Denise  
CC: Mair, Michael; Sadove, Elizabeth; McSeveney, Megan; Beers, Donald; Anderson, Erika  
Subject: RE: Urgent: Information request for ASPR White House Briefing  
Importance: High
Yes, I will send them shortly—I’m in the process of adding the additional information requested below. OCC still needs to review the new information, which I’ve already sent to them.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, February 13, 2020 1:33 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Can I see the slides please?

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 13, 2020 12:53 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

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

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, February 13, 2020 10:52 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Hi Anna,

Thank you for the input.

(b)(5)

(b)(5)

(b)(5)

Thanks,
Brooke

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Thursday, February 13, 2020 10:47 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Plus Keagan
Hi Anna and Denise,

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

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

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

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

Thanks!
Brooke
Good morning,

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

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

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

Many thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) 301-796-0377 (cell)
brooke.courtney@fda.hhs.gov
Any f/u on this during the day?

---

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

Thank you.

---

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

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

---

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

Denise, Michael, Anna,
Please see the request below from China’s National Medical Products Administration for information on the Remdesivir protocol and advise on a response.
Thanks,
Abdoo
Here is the request by NMPA I referenced in my earlier message.

Lane

-------- 原始信息 --------
发件人： 刘袁 <liuyuan@nmpa.gov.cn>
日期：2020/2/13 17:46 (GMT+08:00)
收件人： "Wang, Lixia (Beijing)" <WangLX@state.gov>
抄送： liujq <liujq@nmpa.gov.cn>, qinxl <qinxl@nmpa.gov.cn>
主题： Remdesivir 相关信息核实

王老师，您好！
有个情况需要请FDA协助确认一下。我们最近获知，吉利德公司的产品瑞德西韦用于治疗新型冠状病毒肺炎的临床方案需要经过美国FDA批准后，方可将产品出口到中国，而FDA已于近日批准了这一临床方案，因此临床试验用瑞德西韦可以向中国出口。
希望FDA驻华办协助核实相关情况。情况紧急，希望今晚能与美国国内联系，明日回复为盼！

Dear Lixia,

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

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

Thank you for your help!

--
LIU Yuan
Division of Bilateral Cooperation, Department of Science, Technology and International Cooperation
National Medical Products Administration
Tel: 0086 10 88330509
Fax: 0086 10 68337662

刘袁
科技和国际合作司双边合作处
国家药品监督管理局
中国北京西城区展览路北露园1号
电话：0086 10 88330509
传真：0086 10 68337662
From: Courtney, Brooke [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=261A2A3791E24E19B095AC0172485EBD-BROOKE.COUR]
Sent: 2/14/2020 7:29:00 AM
To: Abram, Anna [O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=ee72320ee8c184d66bdf521b0105d17d2-Keagan.Len]; Lenihan, Keagan
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Mair, Michael
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85feca0be0694803be6030e97c7b4ad-HINTOND]; Anderson, Erika
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=98606928b9a64edfb25aba1e3573fdfe-Eranders]
CC: Sadove, Elizabeth [O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE] 
Subject: Fwd: Urgent: Information request for ASPR White House Briefing
Attachments: Placemats-021320.pptx; HHS 14 Feb COVID_19 PCC Slides Supply Chain v5.pptx
Importance: High

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 13, 2020 at 11:49:16 PM EST
To: Patel, Anita (CDC) <bopl@cdc.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, D’alessandro, Maryann M (CDC) <bpj5@cdc.gov>,
Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Schwartz,
Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

All-

I feel lousy about how this slide request evolved.                                       (b)(5)

(b)(5)

Thanks,

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.sgov.gov
Desk: 202-260-0666
Cell (b)(6)
Thanks all – we sent our deck to Laura with a CC to Brooke on another thread.

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

Also:
CDC and FDA spoke today.
FDA and ASPR spoke today.
CDC and ASPR have not spoken.
Pre-brief was done by ASPR staff with no CDC or FDA staff.

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

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

Best,

Jennifer

Jennifer Brown Tomasello, MPA
Senior Policy Advisor
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-5924 - Cell: (b)(6)
jennifer.tomasello@fda.hhs.gov

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U.S. FOOD & DRUG ADMINISTRATION

FDA-OSJI-FOIA-2020-3541_00007148
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https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E

From: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Sent: Thursday, February 13, 2020 10:56 AM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Patel, Anita (CDC) <bopl@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

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Sent: Thursday, February 13, 2020 10:53 AM
To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

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

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

Best,

Jennifer Brown Tomasello, MPA
Senior Policy Advisor
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel. 301-796-8924 - Cell (b)(6)
jennifer.tomasello@fda.hhs.gov

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

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

Sorry and thank you,
TJ

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Sent: Wednesday, February 12, 2020 4:24 PM
To: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D’Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

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

Best,

Jennifer

Jennifer Brown Tomasello, MPA
Senior Policy Advisor
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-8924 - Cell: (b)(6) jennifer.tomasel@fda.hhs.gov

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

From: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 1:35 PM
To: Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D’alessandro, Maryann M (CDC) <bpj5@cdc.gov>
Cc: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks! We will get these done.

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Thank you, and enjoy your vacation!!!

TJ

---

TJ,

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

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

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

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

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

Maryann: what do you think?

Suzanne
Good afternoon,
Would you be able to help with --

Thank you.

v/r,

TJ

From: D’Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Sent: Tuesday, February 11, 2020 8:38 PM
To: Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bopl@cdc.gov>; Dowell, Chad (CDC/NIOSH/OD) <crd7@cdc.gov>; Delaney, Lisa (CDC/NIOSH/OD) <lkd2@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Hello all,

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

Best,

Maryann

Maryann M. D’Alessandro, PhD
Director
HHS/Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety & Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochrans Mill Rd
Building 141, Rm 105
Pittsburgh, PA 15236

Office: (412) 386-4033
Mobile: (b)(5)
bpj5@cdc.gov

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 7:27 PM
To: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Laura,

For the WH briefing, I think it would be very helpful for the ASPR to show a surgical mask and to show an N95 respirator so that lay folks can see and understand the difference.

Suzanne B. Schwartz, MD, MBA  
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)  
Center for Devices & Radiological Health  
US Food & Drug Administration  
Office: 301-796-6937  
Mobile:_________ (b)(6)_________
Tom et al,

CDRH requests that we use the proper nomenclature for N95s as respirators, and not refer to them as N95 ‘masks’. Surgical masks are very different than surgical N95 respirators and it is a critical distinction to make here so as to avoid confusion or conflating the two.

I think what the ASPR would like to have information on is at the very least the first two buckets but probably the third as well:
1. N95 respirators (have met standard testing requirements for NIOSH approval)
2. N95 surgical respirators (have met standard testing requirements for NIOSH approval for N95s PLUS additional FDA requirements so as to be considered medical devices)
3. Surgical masks - these are not respirators and do not provide the same respiratory protection as respirators.

I’m copying Anita Patel from CDC and Maryann D’Alessandro from NIOSH / NPPTL for their comments since how we communicate around these products has to be consistent and aligned with the guidance that CDC puts out, and using the generic term ‘masks’ here very much confuses matters.

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile (b)(6)
Good afternoon,

Dr. Kadlec is briefing the White House this Friday, February 14, on the status (b)(5)

He has requested specific information on (b)(5)

Response requested by 1400 Wednesday, Feb 11, 2020. We apologize for the quick deadline and appreciate your efforts to date to gather this information and to help prepare for this briefing.

Please contact me or Laura for more information on this request.

Thank you.

v/r,

CDR Thomas J (TJ) Christi
U.S. Department of Health & Human Services
Assistant Secretary for Preparedness & Response (ASPR)
Office of Security, Intelligence and Information Management
Division of Critical Infrastructure Protection
Office: 202-260-0680
Cell: (b)(6)
From: Mair, Michael [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FA4C7EDAC7961467AB-MICHAEL.MAI]

Sent: 2/14/2020 7:50:21 AM


Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

Attachments: Draft Statement for SH REVIEW 1-SMH comments AA2013ORA_MM.docx

And from me – use whatever works thx

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>

Sent: Friday, February 14, 2020 7:44 AM

To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Subject: RE: URGENT OCET, ORA, and OCC Review needed by 9am today - Commissioner's statement re: FDA outbreak coronavirus response efforts

A couple of comments from me labeled “FDA” in the comment box. – If you do not hear more from Michael, you can consider it cleared from OCET.

Good morning! The Commissioner reviewed the draft statement on FDA’s coronavirus response efforts and asked for some edits to his talking points. The attached version has the edits from the Commissioner, as well as additional edits made to address his comments. ORA already did a quick review last night to help address those edits – thank you! We are now asking for concurrent ORA, OCC, and OCET review - if possible - by 9am to review and hopefully very quickly finalize these and any additional edits as needed to ensure accuracy. If is not possible to review by 9am could you please flag for this group as soon as possible? Carol and others in ORA, I have tried to address Carol’s edits and respond to any outstanding questions/comments from ORA in the attached and again want to thank you for your help last night. Many thanks to all of your help and please let me know if you have any questions. Thank you!
From: Abram, Anna [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/14/2020 7:53:30 AM
To: Courtney, Brooke [O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebed-Brooke.Cour]; Lenihan, Keagan
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Mair, Michael
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f451bda77564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Anderson, Erika
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2baf4b-SADOVEE]
CC: Sadove, Elizabeth [O=Exchangelabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2baf4b-SADOVEE]
Subject: Re: Urgent: Information request for ASPR White House Briefing

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: February 14, 2020 at 7:29:04 AM EST
To: Abram, Anna <Anna.Abram@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: Fwd: Urgent: Information request for ASPR White House Briefing
Importance: High

(b)(5)

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 13, 2020 at 11:49:16 PM EST
To: Patel, Anita (CDC) <bopl@cdc.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, D’alessandro, Maryann M (CDC) <bpj5@cdc.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

All-

I feel lousy about this slide request evolved. (b)(5)

(b)(5)
Thanks, 

Laura

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

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

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

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

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

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

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

Here is the attachment for Anita, just in case.

Best,

Jennifer
Jennifer Brown Tomasello, MPA
Senior Policy Advisor
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-5924 - Cell: ____________________________
jennifer.tomasello@fda.hhs.gov

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+ anita patel

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

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

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

Best,

Jennifer

Jennifer Brown Tomasello, MPA
Senior Policy Advisor
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-796-5924 - Cell: ____________________________
jennifer.tomasello@fda.hhs.gov
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To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D’alessandro, Maryann M. (CDC) <bj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

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Sorry and thank you,
TJ

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To: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; D’Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

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

Best,

Jennifer

Jennifer Brown Tomasello, MPA
Senior Policy Advisor
Center for Devices and Radiological Health
Office of Policy
U.S. Food and Drug Administration
Tel: 301-795-5924 - Cell: __________
jamie.tomasello@fda.hhs.gov

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https://www.research.net/s/cdrhcustomerservice?ID=5000&S=E
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Sent: Wednesday, February 12, 2020 1:35 PM
To: Christl, Thomas (OS) <Thomas.Christl@hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; D’alessandro, Maryann M (CDC) <bpj5@cdc.gov>
Cc: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thanks! We will get these done.

From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Date: February 12, 2020 at 1:21:47 PM EST
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, D’Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Cc: Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

Thank you, and enjoy your vacation!!!

TJ

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 1:09 PM
To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; D’Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Cc: Ricci, Linda J (FDA/CDRH) <Linda.Ricci@fda.hhs.gov>; Tomasello, Jennifer (FDA/CDRH) <Jennifer.Tomasello@fda.hhs.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

TJ,

(b)(6)

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

Linda and Jennifer: the TPs TJ is asking for are intended to accompany / complement the ASPR’s briefing to WH on Friday and the slide deck that we noted required edits to reflect (b)(5) Because we are inundated with work, it might be most efficient to get help from Liz Claverie for these TPs.

(b)(5)

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

Maryann: what do you think?

Suzanne
Good afternoon,

(b)(5)

Thank you.

v/r,

TJ

FROM: D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
SENT: Tuesday, February 11, 2020 8:38 PM
TO: Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>; Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bopl@cdc.gov>; Dowell, Chad (CDC/NIOSH/OD) <crd7@cdc.gov>; Delaney, Lisa (CDC/NIOSH/OD) <lkd2@cdc.gov>
CC: Schwartz, Suzanne (FDA/CDRH) <Suzanne.Schwartz@fda.hhs.gov>; Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
SUBJECT: RE: Urgent: Information request for ASPR White House Briefing

Hello all,

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

Best,

Maryann

Maryann M. D’Alessandro, PhD
Director
HHS/Centers for Disease Control and Prevention (CDC)
National Institute for Occupational Safety & Health (NIOSH)
National Personal Protective Technology Laboratory (NPPTL)
626 Cochran's Mill Rd
Building 141, Rm 105
Pittsburgh, PA 15236
Office: (412) 386-4033
Laura,

For the WH briefing, I think it would be very helpful for the ASPR to show a surgical mask and to show an N95 respirator so that lay folks can see and understand the difference.

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)

CDC should weigh in here as well

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 11, 2020 at 7:19:41 PM EST
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney J (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Patel, Anita (CDC/NIOSH/NCIRD/OD) <bopl@cdc.gov>, D’Alessandro, Maryann M (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Date: February 11, 2020 at 7:21:04 PM EST
To: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Patel, Anita (CDC) <bopl@cdc.gov>, D’alessandro, Maryann M (CDC) <bpj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 11, 2020 at 7:27:02 PM EST
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Patel, Anita (CDC/NIOSH/NCIRD/OD) <bopl@cdc.gov>, D’alessandro, Maryann M (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Subject: RE: Urgent: Information request for ASPR White House Briefing
Thanks very much for that clarification!

Laura

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

From: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>
Sent: Tuesday, February 11, 2020 7:12 PM
To: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Cc: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>; Seiler, Brittney (OS/ASPR/SIIM) <Brittney.Seiler@hhs.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Patel, Anita (CDC/DDID/NCIRD/OD) <bopl@cdc.gov>; D'Alessandro, Maryann M. (CDC/NIOSH/NPPTL) <bpj5@cdc.gov>
Subject: Re: Urgent: Information request for ASPR White House Briefing
Importance: High

Tom et al,

(b)(5)

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: (b)(6)
From: Christl, Thomas (OS/ASPR/SIIM) <Thomas.Christl@hhs.gov>
Date: February 11, 2020 at 5:46:43 PM EST
To: Patel, Anita (CDC) <bop1@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, McClune, Elizabeth P (CDC) <ymt0@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, FDA Emergency Operations <emergency_operations@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, Ottem, Ronald S (CDC) <rco9@cdc.gov>, Fredenberg, John E (CDC) <dje5@cdc.gov>, Figlio, Joseph (OS) <joseph.figlio@hhs.gov>, Rooks, Mercedes (OS) <Mercedes.Rooks@hhs.gov>, Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>, Angelastro, Michael (OS) <Michael.Angelastro@hhs.gov>
Cc: Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>, Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>
Subject: Urgent: Information request for ASPR White House Briefing

Good afternoon,

Dr. Kadlec is briefing the White House this Friday, February 14, on the status (b)(5) He has requested specific information on (b)(5) Response requested by 1400 Wednesday, Feb 11, 2020. We apologize for the quick deadline and appreciate your efforts to date to gather this information and to help prepare for this briefing.

Please contact me or Laura for more information on this request.

Thank you.

v/r,

CDR Thomas J (TJ) Christl
U.S. Department of Health & Human Services
Assistant Secretary for Preparedness & Response (ASPR)
Office of Security, Intelligence and Information Management
Division of Critical Infrastructure Protection
Office: 202-260-0680
Cell: (b)(6)
Good morning team,

From: Black, Jennifer [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHF23SPDLT)/CN=RECIPIENTS/CN=AAF8A19F3672492293A7C1B2D1498059-JENNIFER.BL]

Sent: 2/14/2020 9:43:32 AM


Subject: RE: Congressional Briefings for 2/14

Attachments: 2.14.20 SUPPLY CHAIN Talking Points Member meeting for Denise.docx; nCoR 2-14-20 General Talking Points and QnA.docx
For our prep calls and briefings today, attached are the documents we will be working from. The first attachment includes the supply chain talking points that Denise will read through on the call. The second attachment contains general talking points for any potential questions.

We will discuss the run of show at our 10:30 internal prep call, including what SMEs should be prepared to discuss. Please be prepared to discuss updates on your relevant medical products.

Thank you all and see/ talk to you soon!

Jen

From: Black, Jennifer  
Sent: Thursday, February 13, 2020 6:25 PM  
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ngan, Kelly <Kelly.Ngan@fda.hhs.gov>; Rouse, David <David.Rouse@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Jodi Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>  
Cc: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>  
Subject: Congressional Briefings for 2/14

Hi team coronavirus,

We just had a prep with some of you this evening and we want to thank you for being willing to join us on such short notice. To recap, we have two Congressional briefings that have been scheduled for tomorrow. We will be briefing Education & Labor and Energy & Commerce at 12:00 and Sen. Cornyn staff at 2:00.

If you were not in the prep today, you were identified as key staff that we should have at the briefings tomorrow to ensure all offices are represented. We are having a prep with ASPR at 10 am tomorrow, followed by an internal FDA prep at 10:30. We will send you all the invites to these. We are waiting for the Commissioner’s statement to be fully cleared until we send around the meeting documents for tomorrow, but we will either send the updated versions around late tonight or tomorrow morning. The documents have already been cleared and RADM Hinton’s opening statements will generally come from the Commissioner’s statement.

We will be in touch soon with the meeting invites and updated documents. Please reach out to any of our team in OL with any questions or concerns.

Thank you for your continued hard work!

Jen

2/14/2020 Interagency Phone Briefing Schedule

10:00-10:30; Prep with ASPR

10:30-11:00; Internal FDA prep
12:00-12:30 pm; Supply Chain Efforts with Education & Labor and Energy & Commerce
FDA SMEs:
- OCS: Denise Hinton
- OMA: Megan McSeveney
- OCET: Liz Sadove
- CDER: Val Jensen, Paras Patel, Rosemary Roberts, Kelly Ngan
- CBER: David Rouse, David Cho
- CDRH: Jennifer Tomasello, Heather Aglar
- ORA: Mike Rogers
- OCC: Don Beers, Dinesh Kumar

2:00-2:30pm; Supply Chain Briefing with Cornyn Staff: Jeff Last
FDA SMEs:
- OCS: Denise Hinton
- OCET: Brooke Courtney
- OMA: Megan McSeveney
- CDER: Val Jensen, Paras Patel, Rosemary Roberts, Kelly Ngan
- CBER: David Rouse, David Cho
- CDRH: Jennifer Tomasello, Heather Aglar
- ORA: Mike Rogers
- OCC: Don Beers, Dinesh Kumar

Jennifer R. Black, J.D.
Congressional Affairs Specialist
Office of Legislation
U.S. Food and Drug Administration
Tel: 301-796-9607
jennifer.black@fda.hhs.gov
From: McSeveney, Megan [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=0D4B7FC0CFED46C7B1BFCDDD41F240D7-MEGAN.MCSEV]

Sent: 2/14/2020 12:23:14 PM


Subject: NEW - Latest version COVID19 statement - Commissioner’s statement re: FDA outbreak coronavirus response efforts

Attachments: CLEANDRFTStatement 0957SIAOCETORAOCCAA 1205pm.docx
Hi all – attached is the latest version of this statement with final input from the Commissioner and Anna that went to HHS for final clearance through HHS and the interagency. While this will get a final proof, I hope that I won’t need to run any more edits by you all. I greatly appreciate all the help. Thank you again!

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

From: Thomson, Kyle <Kyle.Thomson@fda.hhs.gov>
Sent: Friday, February 14, 2020 10:30 AM
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>
Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lynch, Kara P <Kara.Lynch@fda.hhs.gov>; Franz, Lauren <Lauren.Franz@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>
Subject: RE: Latest version COVID19 statement please review by 10:30 - Commissioner's statement re: FDA outbreak coronavirus response efforts

Megan,

Thanks, you did indeed copy the right Kyle from OCC. OCC clears the green highlighted language. Thank you to the task force and others in OCC for their quick turnaround yesterday.

Kyle

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 14, 2020 10:12 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Laska, Susan F <Susan.Laska@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Humbert, Jason <Jason.Humbert@fda.hhs.gov>; Thomson, Kyle <Kyle.Thomson@fda.hhs.gov>
Cc: Burgess, Shelly <Shelly.Burgess@fda.hhs.gov>; Windt, David <David.Windt@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather
Hi all - lots of edits this am. Thank you all! Attached is a version for review that has edits incorporated. We are also waiting to hear if HHS will have edits to reconcile. Anna is planning to review this after 10:30 so any comments before 10:30 would be much appreciated. Attaching the same document in tracked and clean versions. Jason and OCC can you please review the task force efforts I have added and highlighted in green and make sure that I am not crossing the line / that this can be shared. I would love to highlight your work! Kyle, I’m not sure if I identified the right Kyle from OCC working on this - if not - my apologies! Thank you!

Megan McSeveney
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-4514/Cell ________
Megan.McSeveney@fda.hhs.gov
Thank you all- I’ll incorporate this in and send back shortly as we keep this moving. Thanks!

Dinesh
Dinesh Kumar
Office of the Chief Counsel, FDA
Food and Drug Division, OGC/HHS
White Oak Building 32, Room 4377
10903 New Hampshire Ave.
Silver Spring, MD 20993
T 240.402.0372

From: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>
Sent: Friday, February 14, 2020 8:48 AM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Cave, Carol <Carol.Cave@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>
Hi all- I’ll start working on getting the edits from Mark incorporated. Thank you!

Risk based is also for food per FSMA, no?

Apologies – for this not being in the document:
(b)(5)
Good morning! The Commissioner reviewed the draft statement on FDA’s coronavirus response efforts and asked for some edits to his talking points. The attached version has the edits from the Commissioner, as well as additional edits made to address his comments. ORA already did a quick review last night to help address those edits – thank you! We are now asking for concurrent ORA, OCC, and OCET review - if possible - by 9am to review and hopefully very quickly finalize these and any additional edits as needed to ensure accuracy. If is not possible to review by 9am could you please flag for this group as soon as possible? Carol and others in ORA, I have tried to address Carol’s edits and respond to any outstanding questions/comments from ORA in the attached and again want to thank you for your help last night. Many thanks to all of your help and please let me know if you have any questions. Thank you!
Works for me.

Hi – I believe this is referring to the export issue related to remdesivir for the clinical trial in China, which has been resolved and the product exported. It might be best to refer it to the HHS SOC for response...

Denise, Michael, Anna,
Please see the request below from China’s National Medical Products Administration for information on the Remdesivir protocol and advise on a response.
Thanks,
Abdoo
Here is the request by NMPA I referenced in my earlier message.

Lane

-------- 原始信息 --------
发件人： 刘袁 <liuyuan@nmpa.gov.cn>
日期：2020/2/13 17:46 (GMT+08:00)
收件人： “Wang, Lixia (Beijing)” <WangLX@state.gov>
抄送： liujq <liujq@nmpa.gov.cn>, qinxl <qinxl@nmpa.gov.cn>
主题： Remdesivir 相关信息核实

王老师，您好！

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

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

Dear Lixia,

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

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

Thank you for your help!

--
LIU Yuan
Division of Bilateral Cooperation, Department of Science, Technology and International Cooperation
National Medical Products Administration
Tel: 0086 10 88330509
Fax: 0086 10 68337662

刘袁
科技和国际合作司双边合作处
国家药品监督管理局
中国北京西城区展览路北露园1号
电话: 0086 10 88330509
传真: 0086 10 68337662
The attached TP’s may change a bit

http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx

Includes draft responses to questions, which SME’s will convey verbally

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Hello,

We made minor tweaks to the attached documents, and will talk about these and the run of show in a few minutes. We'll bring copies.

Thanks,
Prakash

The attached TP's may change a bit
- http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx
  - Includes draft responses to questions, which SME's will convey verbally

Includes QA from ASPR
-- Do not delete or change any of the following text. --

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Need help? Go to http://help.webex.com
Quick question,

Wasn't the original ask just wanting a confirmation from FDA that the protocol has been approved and product cleared for export? The problem being the expeditious manner that really caught NMPA off guard because FDA took much less than 30 days to review and make a determination. It may have been cleared to leave the US but it is being held up by Chinese authorities.

Lane

Hi – I believe this is referring to the export issue related to remdesivir for the clinical trial in China, which has been resolved and the product exported. It might be best to refer it to the HHS SOC for response...?

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

From: Christensen, Lane <Lane.Christensen@fda.hhs.gov>
Date: February 13, 2020 at 06:09:09 EST
To: Abdoo, Mark <Mark.Abdo@fda.hhs.gov>, Ross, Bruce <Bruce.Ross@fda.hhs.gov>
Cc: Salazar, Julio <Julio.Salazar@fda.hhs.gov>, Gabriela, Celia <Celia.Gabriela@fda.hhs.gov>
Subject: Fwd: Remdesivir 相关信息核实
Importance: High

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

Lane

-------- 原始信息 --------
发件人： 刘燕 <liuyuan@nmpa.gov.cn>
日期： 2020/2/13 17:46 (GMT+08:00)
收件人： "Wang, Lixia (Beijing)" <Wanglx@state.gov>
抄送： liujq <liujq@nmpa.gov.cn>, qinxl <qinxl@nmpa.gov.cn>
主题： Remdesivir 相关信息核实

王老师・您好！

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

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

Dear Lixia,

We hope FDA China office could do us a favor and help to confirm some information. We were informed that the clinical protocol for Remdesivir treating COVID-19 needs to be approved by FDA. And the product Remdesivir cannot be exported to China until the clinical protocol is approved. It is said that the above-mentioned clinical protocol has been recently approved by FDA and therefore, the product Remdesivir for clinical studies can be exported to China afterwards.
Please help to confirm the above information. Due to the urgency of the situation, we hope you could forward the message to FDA tonight and give us some feedback tomorrow, if possible.

Thank you for your help!

--
LIU Yuan
Division of Bilateral Cooperation, Department of Science, Technology and International Cooperation
National Medical Products Administration
Tel: 0086 10 88330509
Fax: 0086 10 68337662

刘袁
科技和国际合作司双边合作处
国家药品监督管理局
中国北京西城区展览路北露园1号
电话: 0086 10 88330509
传真: 0086 10 68337662
Use this version thx

Will review shortly

Sorry it's late...
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/17/2020 8:02:36 AM
To: Mair, Michael [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: Fwd: CDC 2019-nCoV Test Update

Thanks, Michael.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Date: February 17, 2020 at 7:44:18 AM EST
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 17, 2020 at 6:51:39 AM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks Jeff, looking towards today's update.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review. [b](5) (b)(5)

Jeff

Internal confidential
Dear Colleagues,

FDA-OSJ-FOIA-2020-3541_00006920
Please accept this meeting invite for tomorrow afternoon. Given the dynamic nature of the epidemic and the number of ongoing work streams across the USG, there may or may not be a need for this meeting tomorrow and we will let everyone know ASAP. Also, the content for the agenda is evolving and we will distribute and agenda ASAP.

(b)(5)

Participants are expected to attend in person. With exception of CDC Atlanta and NIAD, SVTC connection will be in listen only mode, though D/A are welcome to have additional participants listen in via SVTC for SA. Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

The classification of this meeting will by U//FOUO)

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

We sincerely thank everyone for their flexibility as we address this complex and rapidly evolving issue, and are very appreciative of the huge effort being put forth.

Best Regards,

Phil
Dear Colleagues,

Please accept this meeting invite for tomorrow afternoon. Given the dynamic nature of the epidemic and the number of ongoing work streams across the USG, there may or may not be a need for this meeting tomorrow and we will let everyone know ASAP. Also, the content for the agenda is evolving and we will distribute and agenda ASAP.

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

Please use the WAVES link to register for attendance. https://events.whitehouse.gov/?rd=KQCRWDJ2K8

We sincerely thank everyone for their flexibility as we address this complex and rapidly evolving issue, and are very appreciative of the huge effort being put forth.

Best Regards,

Phil
Dear Colleagues,

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Please use the WAVES link to register for attendance.

We sincerely thank everyone for their flexibility as we address this complex and rapidly evolving issue, and are very appreciative of the huge effort being put forth.

Best Regards,

Phil
From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Monday, February 17, 2020 12:18 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps quad charts

I need to provide to OB by noon Tuesday. Please review the attached and send thoughts and info ASAP. I can work with Center SMEs if need be but would like you to take another stab at it first.

Please let me know when u will be able to get something back to me as I have a zillion things to do and need to plan for getting this done. Thx

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Friday, February 14, 2020 6:21 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Cc: Orr, Robert <Robert.Orr@fda.hhs.gov>
Subject: Fwd: 2019-nCoV regulatory science gaps quad charts

Not sure if you’ve already sent the request forward.

Please let me know if there is any additional information needed.

From: Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>
Date: February 14, 2020 at 5:53:48 PM EST
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>, MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Cc: Anderson, Lori (Henry) <Lori.Anderson@fda.hhs.gov>, CBER OM/BAFB <CBEROMBAFB@fda.hhs.gov>, Leary, Mary <Mary.Leary@fda.hhs.gov>, Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>, Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps quad charts

Tracy,

Sorry for the late email. Let me know if you have any questions.

(b)(5)

Thank you and have a nice weekend,
Emily

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 5:31 PM
To: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Cc: Braunstein, Emily <Emil.Braunstein@fda.hhs.gov>; Anderson, Lori (Henry) <Lori.Anderson@fda.hhs.gov>; CBER OM/BAFB <CBEROMBAFB@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps quad charts

Tracy,

I attached the wrong version of the word document. That’s our internal tracking sheet. Please use this for your purposes.
Thanks,
Carolyn

From: Wilson, Carolyn
Sent: Wednesday, February 12, 2020 5:30 PM
To: MacGill, Tracy
Cc: Braunstein, Emily <Emil.Braunstein@fda.hhs.gov>; Anderson, Lori (Henry) <Lori.Anderson@fda.hhs.gov>; CBER OM/BAFB <CBEROMBAFB@fda.hhs.gov>; Leary, Mary <Mary.Leary@fda.hhs.gov>; Hussey, Deirdre <Deirdre.Hussey@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps quad charts

Tracy,

Attached is a one-page summary of the quad charts that we received. (b)(5)
Please let us know if you need any additional information to support this.

Thank you,

Carolyn

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Wednesday, February 12, 2020 4:37 PM
To: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric. Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Orr, Robert <Robert.Orr@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps quad charts

Ladies and Gentlemen,

While we understand everyone is very busy with CoV-related activities, we wanted to follow up on the status of the quad charts discussed last Monday. Since this information is being requested by COB today, it would be very helpful if you forward the quad charts received to date along with estimated total costs at your earliest convenience.

Sincere apologies for the short turnaround time. Any information you can provide to support this request is greatly appreciated.

Best regards,

Tracy

Tracy MacGill, Ph.D.
CAPT, USPHS
Director, MCM Regulatory Science
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
White Oak, Bldg 1, Rm 4315B
10903 New Hampshire Ave
Takeaways from Monday’s meeting on regulatory science gaps:

(b)(5)

Please let me know if I’ve omitted anything....
Best,
Robert

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-756-8518
(m)814-403-9035
robertfisher@fda.hhs.gov
From: Branch, Tiffany [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDI BO HF 23SPDL T)/CN=RECIPIENTS/CN=845F1B97B5D648F68CDFF5CE4F75A154-TIFFANY.BRA]  
Sent: 2/17/2020 2:33:39 PM  
To: Fobbs, Linda [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=a83b8309e0f1497cb8f3cfaa4ef46f2-Linda.Fobbs]; Yates, Connie [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=43a5f5be748e40f3a48a1167ea568f7-Connie.YeId]; Saunders, Shelisha [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=be12b83443674d87a7e9f87b51654683-Shelisha.Sa]; Biser, Kelley [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=3ab8751f95c34e5a80c9b37a7e2c7b3-KBiser]; Carter, Lionel [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=7b4f0e18bf9d24382b572355f0f15acd-c-Lionel.Cart]; Rebello, Heidi [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=2834ce193ca949799e063e34a2cfa0-Heidi.Reb]; Enoch, Bobby [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=385a224608c04f619542ae28007a2016-Bobby.Enoch]; Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=85feca0be0e694803be030e97c7b4adb-HINTOND]; Green, Jamie [O=ExchangeLabs/OU=Exchange Administrative Group (FYDI BO HF 23SPDL T)/cn=Recipients/cn=39be8c8f54334a3dbcd557b094db159-Jamie.Gre]  
Attachments: Copy of FY 20 to FY 24 Coronavirus Outbreak Spending Estimates.xlsx

Good afternoon,

I just want to make sure this is on everyone’s radar given the short turnaround. We understand that this will just be an estimate given the timeframe.

Best,

Tiffany

From: Tootle, William <William.Tootle@fda.hhs.gov>  
Sent: Saturday, February 15, 2020 1:43 PM  
To: FDA Office of Budget <FDABudgetSummationContacts@fda.hhs.gov>; FDA Budget Formulation Contacts <FDABudgetSummationContacts@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Green, Jamie <Jamie.Green@fda.hhs.gov>; Enoch, Bobby <Bobby.Enoch@fda.hhs.gov>; Yates, Connie <Connie.Yates@fda.hhs.gov>; Buchanan, Noni <Noni.Buchananp@fda.hhs.gov>; Tan, William <William.Tan@fda.hhs.gov>; Akparewa, Amy <Amy.Akparewa@fda.hhs.gov>; Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>  
Cc: FDA Budget Formulation-OB <FDABudgetSummationOB@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Matthews-Ockiya, Swynice <Swynice.Matthews-Ockiya@fda.hhs.gov>; Grant, Leonard D <Leonard.Grant@fda.hhs.gov>; FDA Executive Officers <ExecOfficer@fda.hhs.gov>  

Hi everyone,

I hate to make another change but we are getting a lot of pressure from HHS and OMB to get our input in on Tuesday. That means we need you to provide your input to us by noon on Tuesday.

(b)(5)
Hello Everyone,

We wanted to let everyone know that we received feedback from the centers that the deadline of noon next Tuesday, Feb. 18th, was too aggressive given some staff are out today and also given the holiday weekend. As a result, OB is extending the deadline for the centers and offices to provide their FY 2020 to FY 2024 coronavirus resource estimates via the spreadsheet link below to COB next Wednesday, Feb. 19th, based on feedback we received from the centers. The deadline has also been adjusted in both the “Due Dates” and “Background” sections of the data call below. In addition, a minor correction to a column reference has also been made below in red to step 1 under “Spreadsheet Instructions”. Thanks.
(b)(5)
(b)(5)
(b)(5)
Yes per yesterday’s discussion – thank you.

---

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 7:01 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Yes, I concur with holding off as recommended

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: February 17, 2020 at 6:58:22 PM EST
To: Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

Is the rest of the group good with holding off?

Sent from my iPhone

On Feb 17, 2020, at 6:53 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

Thank you. We will work with Frank in the morning to look for opportunities early next week. Would you like to update the commissioner? Or I can send him a note and cc: this group. Just let me know. Thanks!

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, February 17, 2020 6:44 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>
Cc: Abram, Anna <Anna.Abram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: CDC 2019-nCoV Test Update

If you are recommending pushing, I am fine with that. Sounds like we won’t have this wrapped up with CDC either.
Sent from my iPhone

On Feb 17, 2020, at 6:36 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

I think we could look at early next week as an alternative, but defer to the group. Thank you!

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 5:58 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Taking Jeff off. I don’t have a noon appearing on my calendar – just fyi.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:51 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

We actually moved it to the daily noon, which we did not have today because of the holiday but I can re-up for this small group.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:36 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Taking Dr. Hahn off – the 5:45 appears as cancelled on calendars. Are we still touching base then in addition to the 5:15?

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:35 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Can do then or we also have the comms call at 5:45. LMK your preference.

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Monday, February 17, 2020 3:41 PM
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

We have a 5:15 call that also includes some CDER colleagues for a check in (thanks Denise), do you want this group to touch base before then or cover during 5:15? Happy to do whatever works best for others.

From: Janik, Heather <Heather.Janik@fda.hhs.gov>
Sent: Monday, February 17, 2020 3:39 PM
To: Shuren, Jeff <jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff. I can be available.

From: Shuren, Jeff <jeff.Shuren@fda.hhs.gov>
Date: February 17, 2020 at 3:37:49 PM EST
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

I have an update. It might be better to discuss by phone if folks are available.

Also, below I’m sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

From: Humes, Rosemary (OS/ASPR/BARDA) <Rosemary.Humes@hhs.gov>
Sent: Monday, February 17, 2020 2:04 PM
To: Kuhnert-Tallman, Wendi L (CDC) <wdkl@cdc.gov>; Carroll, Darin S (CDC) <dzuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jfv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@fda.hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@fda.hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA) <richard.schoske.civ@mail.mil>
Subject: Dx development status and RNA prioritization

Dear Dx WG members,

Thanks to all who participated in the call on Friday. I know that everyone is swamped.

A couple of follow up items:

(b)(5)
(b)(5)
From: Shuren, Jeff  
Sent: Sunday, February 16, 2020 11:05 PM  
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>  
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review. (b)(5)

Jeff

Internal confidential
I think our mails crossed, will continue to hold.

Yes, I concur with holding off as recommended.

Is the rest of the group good with holding off?

Sent from my iPhone

Thank you. We will work with Frank in the morning to look for opportunities early next week. Would you like to update the commissioner? Or I can send him a note and cc: this group. Just let me know. Thanks!

If you are recommending pushing, I am fine with that. Sounds like we won’t have this wrapped up with CDC either.
On Feb 17, 2020, at 6:36 PM, Janik, Heather <Heather.Janik@fda.hhs.gov> wrote:

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Sent: Monday, February 17, 2020 5:58 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Taking Jeff off. I don’t have a noon appearing on my calendar – just fyi.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, February 17, 2020 4:51 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

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Subject: RE: CDC 2019-nCoV Test Update

Taking Dr. Hahn off – the 5:45 appears as cancelled on calendars. Are we still touching base then in addition to the 5:15?

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Sent: Monday, February 17, 2020 4:35 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: CDC 2019-nCoV Test Update

Can do then or we also have the comms call at 5:45. LMK your preference.
We have a 5:15 call that also includes some CDER colleagues for a check in (thanks Denise), do you want this group to touch base before then or cover during 5:15? Happy to do whatever works best for others.

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Subject: RE: CDC 2019-nCoV Test Update

Thanks, Jeff. I can be available.

From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Date: February 17, 2020 at 3:37:49 PM EST
To: Hahn, Stephen <SH1@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>
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I have an update. It might be better to discuss by phone if folks are available.

Also, below I’m sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

Jeff

Internal confidential

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Sent: Monday, February 17, 2020 2:04 PM
To: Kuhnert-Tallman, Wendi L (CDC) <wdkl@cdc.gov>; Carroll, Darin S (CDC) <zuz4@cdc.gov>; Beanan, Maureen J (NIH) <beananm@mail.nih.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Villanueva, Julie M (CDC) <jv3@cdc.gov>; Opdyke, Jason A CIV USARMY (USA <jason.a.opdyke.civ@mail.mil>; Wallace, Rodney (OS) <Rodney.Wallace@hhs.gov>; Faison, Tremel (OS) <Tremel.Faison@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Schoske, Richard CIV DTRA J9 (USA <richard.schoske.civ@mail.mil>
Subject: Dx development status and RNA prioritization

Dear Dx WG members,
Thanks to all who participated in the call on Friday. I know that everyone is swamped.
A couple of follow up items:

(b)(5)
(b)(5)
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Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review:

(b)(5)

Jeff

Internal confidential
RE: For Clearance Draft INSIDEFDA FAQs for FDA employees, from Occupational Health

Reviewed and should update with information regarding

From: Tse, Tania <Tania.Tse@fda.hhs.gov>
Sent: Monday, February 17, 2020 6:54 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Barber, Daniel <Daniel.Barber@fda.hhs.gov>
Subject: RE: For Clearance Draft INSIDEFDA FAQs for FDA employees, from Occupational Health

Good evening,

Angel and I reviewed and had a chance to discuss this evening. We don’t have additional comments. The responses seem reasonable and in keeping with known information: (b)(5)

Thanks - Tania

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Date: February 14, 2020 at 5:27:25 PM EST
To: McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Janik, Heather

RE: For Clearance Draft INSIDEFDA FAQs for FDA employees, from Occupational Health
For leadership review – particularly OO. Please provide feedback ASAP. TY

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

Draft InsideFDA FAQs for FDA employees, from Occupational Health

(b)(5)
(b)(5)

Additional questions? Contact FDA Occupational Health Services at 240-402-9177.

###
Hi Denise,

I’m still trying to get confirmation regarding this weekly Tues/Thursday 1pm all hill briefings from the Dept. The format tomorrow looks like it will be the same as the last four we did. We’ll bring TP’s and can come to your office if that sounds good.

Thank you,
Prakash
Right now, this virus is not spreading in the community in the United States and the vast majority of Americans have a low risk of exposure. CDC and the US Government have acted to detect and minimize introduction of the virus into the United States. Our scientists and public health experts are learning more about the virus using the data we have from China and the cases we have here.

**New since Wednesday:**
- The 14th and 15th U.S. cases of COVID-19 were confirmed by CDC on Wednesday and Thursday at Marine Corps Air Station Miramar (California) and Lackland Air Force Base (Texas), respectively. The case identified at Lackland marks the first case in Texas, and brings the number of U.S. states with confirmed cases to seven.
- There will be a Two-Part Webinar Series on Legal Preparedness for COVID-19, beginning next week on **February 18, 1:00 PM ET**: RSVP here.
- CDC Developed Several New Fact Sheets:
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  - What the Public Should Do, English
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- Find the CDC Digital Press Kit on COVID-19, including links to the latest media telebriefings here.

**U.S. Stats**

People Under Investigation (PUI) in the United States since January 21, as of 7:00 PM February 13, 2020: **443**
- Positive test results: **15**
- Negative test results: **347**
- Test results pending\(^1\): **81**

\(^1\)Includes specimens received & awaiting testing, as well as specimens en route to CDC

States & territories with PUI: **42**

**International Stats:**
- Number of Global Locations with Confirmed Cases: **25** (view locations with confirmed cases here)
- Countries with confirmed person-to-person transmission outside of China: **Thailand, Japan, Singapore, South Korea, Malaysia, Germany, United Kingdom, France, Spain, United Arab Emirates, and the U.S.**

**Other Helpful Information for Constituents:**
Here are helpful links to information for your constituents about coronavirus, including important steps they can take to prevent the spread of the disease:
- Guidance on Prevention and Control
- Guidance for Travelers
- Guidance for Ships
- Transmission
- Information for Health Care Providers
- Symptoms & Complications
- CDC Laboratory Test Kits
- 2019-nCoV Infection Control Guidance
- Frequently Asked Questions and Answers

For questions about CDC’s response to COVID-19, please contact the CDC Washington Office at
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Friday, February 14, 2020

Upcoming Briefings/Events:
- Interagency Telebriefing for Hill Staff on COVID-19,
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Situation Update:
There have been 15 cases of COVID-19 confirmed in the United States, including two cases of transmission to people who had not recently been to China. Two U.S. cases have been identified since Wednesday.

Right now, this virus is not spreading in the community in the United States and the vast majority of Americans have a low risk of exposure. CDC and the US Government have acted to detect and minimize introduction of the virus into the
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International Stats:
- Confirmed Cases Globally: 46,997, as of Feb. 13
- Number of Global Locations with Confirmed Cases: 25 (view locations with confirmed cases here)
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Hello,

We made minor tweaks to the attached documents, and will talk about these and the run of show in a few minutes. We'll bring copies.

Thanks,
Prakash

The attached TP’s may change a bit
- [http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx](http://sharepoint.fda.gov/orgs/OC-OL/corona/Essential%20Documents/Senate%20HELP%20Bipar%20QnA.docx)

- Includes draft responses to questions, which SME’s will convey verbally

Includes QA from ASPR

--- Do not delete or change any of the following text. ---

When it's time, join your Webex meeting here.

**Meeting number (access code): [b](6)**

**Meeting password: [b](6)**
Join by phone
Tap to call in from a mobile device (attendees only)
+1-210-795-0506 US Toll
+1-877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to http://help.webex.com
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From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 10:06 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: RE: BARDA Coronavirus support

Here is a powerpoint to go along with the timeline document.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?id=1800&S=E

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 10:04 AM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: RE: BARDA Coronavirus support

Thanks Jeff,

The BARDA plan that is supported by OHT7 is attached. They are not seeking financial support but just support for the attached plan as they are.

(b)(5)

Best,
From: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 10:01 AM
To: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: Re: BARDA Coronavirus support

What support are they seeking from FDA?

Adding Keagan, Anna, and Denise for awareness.

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Date: February 18, 2020 at 9:08:13 AM EST
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>
Cc: Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>
Subject: BARDA Coronavirus support

Hi Jeff,

Rosemary Humes from BARDA has reached out to Uwe and me and asked for support in their plans to: (b)(5)

I am in the process of generating text language for this support to send you this morning. She is wondering if we can get FDA support up through the Commissioner and on up to the Department as needed. She is asking for CDC support too and if there is a CDC call today, I am going to jump on that. She asked me if CMS and/or CLIA could also support but I was unsure of who and how strong their knowledge would be and if they could add something.
Thanks!

Best,

Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov

Jennifer Campbell
Administrative Assistant

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

CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1900&S=E
Thx – sorry late
Use this version – just a couple of copy edits.

From: Mair, Michael
Sent: Tuesday, February 18, 2020 4:53 PM
To: Helms Williams, Emily
Cc: Hinton, Denise; Abram, Anna; Measer, Gregory
Subject: sitrep

Thx – sorry late
Thanks Laura.

Per KL’s timing, we will set for after AEG and sync as needed during the day. Invite to follow.

My preference is to meet immediately following the evening AEG, 0830 or after the Commissioner’s 0900 call but will go with the majority if the vote for mid-day meetings prevail. I will adjust my calendar accordingly.

Thanks,

Denise

Days are really tough for me. I could do mornings or early evenings.
That was the intent of pulling to noon to cover forward leaning and clearing pending. Could you all identify a time mid day. Throwing out 1pm as a new starting point -please lmk avail or other preferences.

8:30 is fine, but if it is morning of are we already a step behind?

I am thinking right after the AEG normally, but it could be we have to connect with SH right after like we did today. Open to peoples thoughts? Before 9am?

We moved our time up to noon and it is not working for Anna, KL or Denise. So, please lmk when the best brief out time is for you all and we will move.

Minus Jeff, plus Erika
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Can do then or we also have the comms call at 5:45. LMK your preference.

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Thanks, Jeff. I can be available.

I have an update. It might be better to discuss by phone if folks are available.

Also, below I’m sharing for your awareness an email sent to CDC/FDA/NIH from Rosemary Humes at BARDA regarding interest in point-of-care testing and the development of a one-pager and slides.

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Internal confidential

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Subject: Dx development status and RNA prioritization

Dear Dx WG members,
Thanks to all who participated in the call on Friday. I know that everyone is swamped.

A couple of follow up items:

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Sent: Sunday, February 16, 2020 11:05 PM
To: Hahn, Stephen <SH1@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: CDC 2019-nCoV Test Update

CDC submitted their request for a new cut-off this evening. The CDRH team finished their review (b)(5) (b)(5) (b)(5).

Jeff

Internal confidential
From: Walsh, Sandy /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP [FYDIBOHF23SPDLT]/CN=RECIPIENTS/CN=C61503C4E7884FC28B9EF6CB8F2514EC-SANDY.WALSH]

Sent: 2/19/2020 12:47:48 PM

To: Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Abram, Anna /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=fb77660891384232a7cd9086fcb9b1a3b-Anna.Abram]; Lenihan, Keagan /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=ee7320ee8c184d66bdf521b0105d17d2-Keagan.Leni]

CC: Rebello, Heidi /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caliguiri, Laura /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=a086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caccamo, Stephanie /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; McSeveney, Megan /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=0d4b7fc0ced1d46c7b1bcfd47f240d7-Megan.McSev]; Lynch, Sarah /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=d24ee4a4f6241f48110d6b35e6704ed-Sarah.Lynch]

Subject: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Attachments: 20200219_Readout FIB SMH ASPR SOC - OCC cleared.docx

Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

\[(b)(5)\]
Good afternoon,

To ensure we are aligned with the Centers as we move forward, I would like to forward the SITREP document to the Center EOs on a daily basis following the Executive Meeting at 5:15. Since we are no longer having daily EO calls, this will ensure their Directors have already reviewed the information, but provide EOs with some context for the discussions they are having with their leadership. If you have no objections, I will begin the process today.

Best,
Tiffany
From: Abram, Anna [O=EXCHANGELABS/O=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FB77660891384232A7CD9086FCBB1A3B-ANNA.ABRAM]
Sent: 2/19/2020 2:44:06 PM
To: Caliguiri, Laura [O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=aa086f2d6c0346e49e996932d86ac62e-laura.calig]; Walsh, Sandy
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=c61503c4e7884fc28b9ef6cb8f2514e-sandy.walsh]; Hinton, Denise
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=85feca0be0694803be6030e97c7b4adb-hintonnd]; Lenihan, Keagan
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=ee7320ee8c184d66bf52b1b0105d17d2-keagan.lenihan]; Rebello, Heidi
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=2834ce193ca949799ef063e34a2cfa0b-heidi.rebello]; Caccamo, Stephanie
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=950c32cebc4b4f080b302c50cf31c8524-stephanie.c]; McSeveney, Megan
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=0d4b7fc0ced46c7b1bcfcd41f240d7-megan.mcseveney]; Lynch, Sarah
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=d24ee4a4f6241f48110db53e6704ed-sarah.lynch]
CC: Rebello, Heidi [O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=2834ce193ca949799ef063e34a2cfa0b-heidi.rebello]; Caccamo, Stephanie
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=950c32cebc4b4f080b302c50cf31c8524-stephanie.c]; McSeveney, Megan
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=0d4b7fc0ced46c7b1bcfcd41f240d7-megan.mcseveney]; Lynch, Sarah
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=recipients/cn=d24ee4a4f6241f48110db53e6704ed-sarah.lynch]
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Just seeing this as I have been in meetings with the Commissioner. Can try and turn around by 3:30 (Sec mtg)

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 2:39 PM
To: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna
<Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McSeveney,
Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Denise Anna and KL
Let us know if 3pm is a reasonable turnout or what will work for you. TY.
Laura

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 12:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan
<Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie
<Stephanie.Caccomo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah
<Sarah.Lynch@fda.hhs.gov>
Subject: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please
provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

(b)(5)
Some suggested changes:

(b)(5)
Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

(b)(5)
(b)(5)
From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 12:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC
Attachments: 20200219_Readout_FIB_SMH_ASPR_SOC_-_OCCAA_cleared.docx

Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

(b)(5)
(b)(5)
Thanks – I agree with suggested edits.

Denise

---

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 3:01 PM
To: Abram, Anna <Anna.Abram@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Subject: RE: For clearance by 3:00 pm - FDA In Brief on SMH visit to SOC

Thanks all. Will make the edits and get this into HW for tonight.

Heidi, re: the photo, we are checking to see what else is available.
Suggested edits in the attached

Good afternoon, attached for your review is the FDA In Brief readout from the recent visit to the SOC. Please provide comments/edits by 3:00 p.m. today. Thank you.

The text is also pasted below.

(b)(5)
(b)(5)
(b)(5)
today’s SITREP

Attachments: 19_2019-nCoV Outbreak_FDA SITREP_19 February 2020.docx
Subject: SARS-CoV-2
Attachments: Agenda 20 Feb FINAL.docx
Location: SVTC and Room 381 for EOP Staff

Start: 2/20/2020 10:00:00 AM
End: 2/20/2020 11:00:00 AM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

Please accept this invite for a virtual meeting tomorrow morning from 1000-1100. There are no rooms available, so EOP staff are welcome to join in room 381 in SAP Ruggiero’s office.

Please find the agenda attached.

All the best,

Phil
Subject: SARS-CoV-2
Attachments: Agenda 20 Feb_FINAL.docx
Location: SVTC and Room 381 for EOP Staff
Start: 2/20/2020 10:00:00 AM
End: 2/20/2020 11:00:00 AM
Show Time As: Tentative

Dear Colleagues,

Please accept this invite for a virtual tomorrow morning from 1000-1100. There are no rooms available, so EOP staff are welcome to join in room 381 in SAP Ruggiero’s office.

Please find the agenda attached.

All the best,

Phil
Subject: SARS-CoV-2
Attachments: Agenda 20 Feb 10:00:00 AM
Location: SVTC and Room 381 for EOP Staff
Start: 2/20/2020 10:00:00 AM
End: 2/20/2020 11:00:00 AM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

Please accept this invite for a virtual tomorrow morning from 1000-1100. There are no rooms available, so EOP staff are welcome to join in room 381 in SAP Ruggiero’s office.

Please find the agenda attached.

All the best,

Phil
From: Hodnette, Jonathan /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
[FYDIBOHF23SPDLT]/CN=RECIPIENTS/CN=EEA0FF4C9FE6418EA8BF16A891DB85B9-JONATHAN.HO

Sent: 2/20/2020 9:32:54 AM

To: Agler, Heather L /o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIBOHF23SPDLT]/cn=RECIPIENTS/cn=090e915048c74139ab1e0f11e16f05ea-HLAA; Hinton, Denise
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIBOHF23SPDLT]/cn=RECIPIENTS/cn=85feca0be0694803be6030e97c7b4ad-HINTOND; Rogers, Michael
/o=ExchangeLabs/ou=Exchange Administrative Group

[417x2]FDA-OSJI-FOIA-2020-3541 _00000438
Hi all,

Thank you for sticking with us as this briefing moved around and came together rather quickly. OMA provided us some updated TPs last night that we have attached and used to make updates to Denise’s opening remarks. We will bring copies to the briefing, and we will be there in advance of the briefing should anyone have any questions you’d like to discuss ahead of time.

Best,

Jon

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

From: Hodnette, Jonathan
Sent: Tuesday, February 18, 2020 1:19 PM
To: Hodnette, Jonathan; Agler, Heather L; Hinton, Denise; Rogers, Michael; Laska, Susan F; Jensen, Valerie E; Schipper, Jodi; Andrew Tantillo (Andrew.Tantillo@fda.hhs.gov); Rath, Prakash (FDA); Black, Jennifer; Luebke, Yasemin; Aguilar, Paul; Rahuwanshi, Rakesh; Tomasello, Jennifer; Pennington, Caitlin; Shirley, Mayo; Van Pool, Kendall; Briefing0L@sharepoint.fda.gov; Oxner, Julie (OS); Rybak, Bailey (OS/ASPR/OEA); Pence, Laura (OS); Kehoe, Brian (OS); Honig, Esther (OS); McSeveney, Megan; Sadove, Elizabeth; Rouse, David; Kumar, Dinesh; Cho, David S (CBER); Tierney, Julia
Cc: 2019-nCoV FDA IMG Planning; Measer, Gregory; Courtney, Brooke; Mair, Michael; Mignon, Alfred; Shuy, Bryan (OS/ASPR/OI); Ross, Aftin; Malais, Tanya; Adams, Steven A. (CDC/SNS/DSNS)
Subject: Phone Briefing HSGAC COVID-19
When: Thursday, February 20, 2020 12:00 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: WO32, Rm 1305 and WebEx

Time confirmed with Committee staff.

This briefing was requested by Senate HSGAC Minority staff (b)(5)

(b)(5) (i.e. RADM Hinton will provide opening remarks and SMEs to provide support for QA).

-- Do not delete or change any of the following text. --

When it’s time, join your Webex meeting here.

Meeting number (access code): (b)(6)
Meeting password: (b)(6)

Join meeting
Join by phone
Tap to call in from a mobile device (attendees only)
210-795-0506 US Toll
877-465-7975 US Toll Free
Global call-in numbers | Toll-free calling restrictions

If you are a host, go here to view host information.

Need help? Go to http://help.webex.com
Denise,

As background for the meeting tomorrow morning, and as you requested, attached is the document Liz and I prepared. My understanding from Tim Stenzel is that FDA is...

Thanks,

Jennifer

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

From: Campbell, Jennifer <Jennifer.Campbell@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 10:05 AM
To: Campbell, Jennifer; Stenzel, Timothy; Hillebrenner, Elizabeth J; Brenner, Sara; Lowe, Toby A; lademarco, Michael (CDC); Ramsey, Melanie R (CDC); Salerno, Reynolds M (CDC); Sen, Oishee (CDC); Burns, Annina (CDC); King, Veronnica (CDC); Howard, Stacy M (CDC); Hinton, Denise; Pillai, Segaran; Scherf, Uwe; Monroe, Stephan S (CDC)
Cc: Gross, Karas; Paulos, Lauren; Flannery, Ellen; Tomasello, Jennifer; Shuren, Jeff; Rubinstein, Wendy; Ross, Jennifer; Sadove, Elizabeth

Subject: FDA/CDC Visit

When: Friday, February 21, 2020 8:45 AM-12:15 PM (UTC-05:00) Eastern Time (US & Canada).
Where: 10903 New Hampshire Ave, Silver Spring MD, White Oak Bldg 66 Room 5425

8:45 - 9 am - Arrive and setup

1. 9:30 am - VALID Act and LDTs
2. 9:30-10 am - Sufficiency of CLIA
3. 10-11 am EUA
4. 11 am – 12 pm - Biosafety (including with IVD)

12-12:15 pm – Discuss planning of next meeting
Hi Denise,

We've sent a lot of emails and requests in the past couple of days and just wanted to make sure you were comfortable and ok with today's plan.

- **HSGAC briefing – 12PM:** Attached are your opening remarks for the noon briefing. (b)(5) I understand that you may have to leave early, and we will fill you in if there is any follow up.

  - Jon and I will be in the FDA-Track room (32-1305) Please feel free to join us early if you would like to go over anything.
  - ASPR will be on the call, and for your awareness the following folks will join:
    - Bryan Shuy, Deputy Assistant Secretary for Preparedness and Response
    - Steve Adams, Director of the Strategic National Stockpile
    - Dr. Laura Wolf, Director of Critical Infrastructure Protection

- **Bicameral hill briefing 1PM:** I will join you in your office for the next briefing. You do not need to give remarks. If questions for FDA come up, we will pull from the TP’s on the second attachment.

Please let us know if you have any questions, see you soon.

Thank you,
Prakash
From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 9:46 AM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR

GM All:
Sharing the NCTR Coronavirus Proposal that has been submitted to OBFA. Per a conference call today, this will be discussed with DHHS & OMB as soon as tomorrow.

Thanks,
Charlotte

“A lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good just because it’s accepted by a majority.”  Booker T. Washington

From: Ashcraft, Charlotte
Sent: Thursday, February 20, 2020 10:48 AM
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR Proposal

GM AI:
Sharing the NCTR Coronavirus Proposal that has been submitted to OBFA. Per a conference call today, this will be discussed with DHHS & OMB as soon as tomorrow.

Thanks,
Charlotte

“...”
Charlotte

“A lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good just because it’s accepted by a majority.” Booker T. Washington

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 9:12 AM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Here you are.

William Douglas Craft  
Management Analyst  
Office of Management  
National Center for Toxicological Research,  
U.S. Food and Drug Administration,  
Phone: 870-543-7250  
william.craft@fda.hhs.gov

The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Craft, William  
Sent: Wednesday, February 19, 2020 8:20 AM  
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>  
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>  
Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

Thanks,

William Douglas Craft  
Management Analyst  
Office of Management  
National Center for Toxicological Research,  
U.S. Food and Drug Administration,  
Phone: 870-543-7250  
william.craft@fda.hhs.gov

FDA-OSJI-FOIA-2020-3541_00000380
Hi Doug,

Please do (b)(5)

Thank you!

Marli,

Take a look at these and make sure I have captured everything. (b)(5)

Keep in mind that this (b)(5)

Thanks for getting these estimates to me.

Feel free to call if you have any questions.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov

The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.
From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:54 AM
To: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Sorry,

(b)(5)

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:51 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

I didn’t see any (b)(5)

Can you provide me this info asap?

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

The contents of this message are those of the sender and they do not reflect any position of the Government or FDA.

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 2:59 PM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>; Foley, Steven <Steven.Foley@fda.hhs.gov>; Cerniglia, Carl <Carl.Cerniglia@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Thank you
Marli, yes, go ahead and move forward.

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research

"The contents of this message are mine and do not reflect any position of the U.S. Food & Drug Administration."

I'd like to try, if Tucker agrees.

Marli

GM All:
The data call is due today. If you want to work with Doug Craft to put together an estimate for a project, I’m happy to submit. (b)(5)

Thanks
Charlotte

Thanks
Charlotte
Tucker

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research

"The contents of this message are mine and do not reflect any position of the U.S. Food & Drug Administration."

From: Tucker Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:58 AM
To: Marli Azevedo <Marli.Azevedo@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Should we work to put one together for NCTR?

Marli

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:36 AM
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric. Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi – just to close the loop on this – no need to this info to me as I understand each Center/office will be capturing its reg sci needs in its own budget line as opposed to submitting a consolidated reg sci request.

That said – OB would like to see a compiled list for reg sci – happy to help compile if folks want to send along info on our request. Thx

From: Mair, Michael
Sent: Monday, February 17, 2020 10:20 AM
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi – just to close the loop on this – no need to this info to me as I understand each Center/office will be capturing its reg sci needs in its own budget line as opposed to submitting a consolidated reg sci request.

That said – OB would like to see a compiled list for reg sci – happy to help compile if folks want to send along info on our request. Thx
From: Fisher, Robert <Robert.Fisher@fda.hhs.gov>
Sent: Wednesday, February 5, 2020 12:14 PM
To: Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: 2019-nCoV regulatory science gaps

Takeaways from Monday’s meeting on regulatory science gaps:
Please let me know if I've omitted anything....
Best,
Robert

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-796-8518
(r)______(b)(5)______
robert.fisher@fda.hhs.gov
From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 10:57:28 AM
To: Ashcraft, Charlotte [/o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3defa923607424z4aced487d77b09b47-e2msashcraft]; Slikker, William [/o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-wslikker]; Patterson, Tucker [/o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c998691c7907864d7d-tpatterson]; Cason, Winona [/o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34304073fc4cc4b578c59ca60a5da91f8-Winona.Caso]
Subject: RE: 2019-nCoV regulatory science gaps NCTR Proposal

Thank you, Charlotte.

Best,
Denise

---

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 10:48 AM
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR Proposal

GM All:
Sharing the NCTR Coronavirus Proposal that has been submitted to OBFA. Per a conference call today, this will be discussed with DHHS & OMB as soon as tomorrow.

Thanks,
Charlotte

“An lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good just because it’s accepted by a majority.” - Booker T. Washington

---

From: Ashcraft, Charlotte
Sent: Thursday, February 20, 2020 9:46 AM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps NCTR

GM All:

(b)(5)
Thanks,
Charlotte

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From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Thursday, February 20, 2020 9:12 AM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Here you are.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov

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From: Craft, William
Sent: Wednesday, February 19, 2020 8:20 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)

Thanks,

William Douglas Craft
Management Analyst
Hi Doug,

Please do: [Blank]

Thank you!

Marli,

Take a look at these and make sure I have captured everything. [Blank]

Keep in mind that this [Blank]

Thanks for getting these estimates to me.

Feel free to call if you have any questions.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
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Sent: Wednesday, February 19, 2020 7:54 AM
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Subject: RE: 2019-nCoV regulatory science gaps

Sorry,

(b)(5)

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:51 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

I didn’t see any: (b)(5)

Can you provide me this info asap?

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research, U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>; Foley, Steven <Steven.Foley@fda.hhs.gov>; Cerniglia, Carl <Carl.Cerniglia@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Thank you

From: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 8:32 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli, yes, go ahead and move forward.

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research

"The contents of this message are mine and do not reflect any position of the U.S. Food & Drug Administration."

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To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

I'd like to try, if Tucker agrees.

Marli

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To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
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GM All:
The data call is due today. If you want to work with Doug Craft to put together an estimate for a project, I’m happy to submit.

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From: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>
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To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli, I am running this by Charlotte to get her opinion. Thanks.

Tucker

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research

U.S. FOOD & DRUG ADMINISTRATION

"The contents of this message are mine and do not reflect any position of the U.S. Food & Drug Administration."

From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:58 AM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>
Subject: FW: 2019-nCoV regulatory science gaps

Should we work to put one together for NCTR?

Marli

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 7:36 AM
To: Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Cho, David S (CBER) <David_CHO@fda.hhs.gov>; Hatwell, Karen <Karen.Hatwell@fda.hhs.gov>; McDermott, Susan <Susan.McDermott@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Olson, Eric <Eric.Olson@fda.hhs.gov>; Parish, Mickey <Mickey.Parish@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Orr, Robert <Robert.Orr@fda.hhs.gov>; MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>; Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>; Raghuwanshi, Rakesh <Rakesh.Raghuwanshi@fda.hhs.gov>
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Subject: RE: 2019-nCoV regulatory science gaps

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That said – OB would like to see a compiled list for reg sci – happy to help compile if folks want to send along info on our request. Thx

From: Mair, Michael
Sent: Monday, February 17, 2020 10:20 AM
Thx for your assistance. – m

Takeaways from Monday’s meeting on regulatory science gaps:
Please let me know if I’ve omitted anything....
Best,
Robert

Robert W. Fisher, Ph.D.
Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-796-8518
(m)____(b)(6)___
robertfisher@fda.hhs.gov
Thanks Tucker. That is correct. 

Thanks,
Charlotte

“A lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good just because it’s accepted by a majority.” Booker T. Washington

Denise,

Thanks.

Tucker

Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research

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Many thanks to all of you.
From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>  
Sent: Thursday, February 20, 2020 10:48 AM  
To: Slikker, William <William.Slikker@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Subject: FW: 2019-nCoV regulatory science gaps NCTR Proposal

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Sharing the NCTR Coronavirus Proposal that has been submitted to OBFA. Per a conference call today, this will be discussed with DHHS & OMB as soon as tomorrow.

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GM All:

(b)(5)

Thanks,  
Charlotte

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Here you are.

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Phone: 870-543-7250
william.craft@fda.hhs.gov

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From: Craft, William
Sent: Wednesday, February 19, 2020 8:20 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Thanks,

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U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov

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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:10 AM
To: Craft, William <William.Craft@fda.hhs.gov>

(b)(5)
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi Doug,

Please do (b)(5)

Thank you!

From: Craft, William <William.Craft@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 8:06 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Cc: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

Take a look at these and make sure I have captured everything. The data call is asking for (b)(5)

(b)(5)

Keep in mind that this (b)(5)

Thanks for getting these estimates to me.

Feel free to call if you have any questions.

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov

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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Wednesday, February 19, 2020 7:54 AM
To: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Sorry,

(b)(5)
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Sent: Wednesday, February 19, 2020 7:51 AM
To: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Marli,

I didn’t see any (b)(5) info. Can you provide me this info asap?

Thanks,

William Douglas Craft
Management Analyst
Office of Management
National Center for Toxicological Research,
U.S. Food and Drug Administration,
Phone: 870-543-7250
william.craft@fda.hhs.gov

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From: Azevedo, Marli <Marli.Azevedo@fda.hhs.gov>
Sent: Tuesday, February 18, 2020 2:59 PM
To: Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>; Matson, Sandra <Sandra.Matson@fda.hhs.gov>; Foley, Steven <Steven.Foley@fda.hhs.gov>; Cerniglia, Carl <Carl.Cerniglia@fda.hhs.gov>
Cc: Craft, William <William.Craft@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Thank you

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Cc: Craft, William <William.Craft@fda.hhs.gov>
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I’d like to try, if Tucker agrees.

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(b)(5)

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Tucker A. Patterson, Ph.D.
Associate Director for Science & Policy
National Center for Toxicological Research

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Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Goering, Peter L. <Peter.Goering@fda.hhs.gov>; Myers, Todd <Todd.Myers@fda.hhs.gov>
Subject: RE: 2019-nCoV regulatory science gaps

Hi – just to close the loop on this – no need to this info to me as I understand each Center/office will be capturing its reg sci needs in its own budget line as opposed to submitting a consolidated reg sci request.

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Subject: RE: 2019-nCoV regulatory science gaps

(b)(5)
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Thx for your assistance. – m
Please let me know if I've omitted anything....

Best,

Robert

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Senior Advisor for CBRN and Pandemic Influenza
Office of Counterterrorism and Emerging Threats (OCET)
Office of the Chief Scientist, Office of the Commissioner
U.S. Food and Drug Administration
(w)301-796-8518
(m) _______ _______ _______
robertfisher@fda.hhs.gov

FDA U.S. Food & Drug
Administration
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF235PDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 2:17:23 PM
To: Rath, Prakash (FDA) [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF235PDLT)/cn=Recipients/cn=91bc5673db6c416e87a4f3f889527cc0-Pra kash.Rat]
Subject: Re: Upcoming COVID Congressional Engagement

Thank you!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Date: February 20, 2020 at 1:52:50 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: Upcoming COVID Congressional Engagement

Hi Denise, I think this is what you were referring to.

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Date: February 20, 2020 at 12:10:09 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Rogers, Michael <Michael.Rogers@fda.hhs.gov>, Berkowitz, Lauren <Lauren.Berkowitz@fda.hhs.gov>, Mettler, Erik <Erik.Mettler@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>
Subject: Upcoming COVID Congressional Engagement

A JIC colleague asked for a list of the hearings we discussed today. The list with some additions is below:

Feb. 18: Briefing for Senate HELP Committee – follow-up questions are pending for JIC clearance by COB today

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Feb. 20: Interagency briefing for all congressional staff – RADM Hinton will be among representatives from many other agencies to answer questions

Feb. 25: In-person interagency briefing for Senators – Dr. Hahn will represent FDA

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Likely: Hearing of the House Oversight and Reform Committee – Dr. Hahn would be the likely witness

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Possible: Hearing of the Senate Homeland Security and Government Affairs Committee - Dr. Hahn would be the likely witness

Andrew Tantillo
Deputy Director
Office of Legislation
U.S. Food and Drug Administration
301-796-8919 (b)(6)
andrew.tantillo@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION
thx
Hi

Here are some talking points.

FDA Coronavirus Request

(b)(5)
Here are some draft talking points for Keagan and Denise.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579
Hi

Here are some talking points.

**FDA Coronavirus Request**

\[(b)(5)\]
Here are some draft talking points for Keagan and Denise.

Bill Tootle

Director, Office of Budget
U.S. Food and Drug Administration
4041 Powder Mill Road,
Beltsville, MD 20705

Phone: 301-796-4710/4579
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/20/2020 7:18:15 PM
To: Mair, Michael /o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai
Subject: READ: FOR CLEARANCE: Tweets for tomorrow- general and PHS All Hands promotion

From: Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Sent: Thursday, February 20, 2020 4:01 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Ruberry, Erin <Erin.Ruberry@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: FOR CLEARANCE: Tweets for tomorrow- general and PHS All Hands promotion

Hi All,

Here are the suggested tweets for tomorrow's social media. Please review for your clearance and let me know if I should send on to Brad. I will be away from my computer after 7 p.m. tonight for a work function, but Brooke (copied here) can send anything forward in my absence.

Thanks very much,
Abby

(b)(5)
(b)(5)
I’ll be attending the Hill briefings with Dr. Hahn on the highlighted days below – don’t have times yet so sending for your awareness and our planning.

From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTON]
Sent: 2/20/2020 7:23:44 PM
To: Shirley, Mayo [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cade42ab7ea7450e8f925908ad26db52-MSHIRLEY]
Subject: FW: Upcoming COVID Congressional Engagement

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Date: February 20, 2020 at 12:10:09 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: OC OCOD Contacts <OCOCODContacts@fda.hhs.gov>, Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Rogers, Michael <Michael.Roers@fda.hhs.gov>, Berkowitz, Lauren <Lauren.Berkowitz@fda.hhs.gov>, Mettler, Erik <Erik.Mettler@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>
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Andrew Tantillo
Deputy Director
Office of Legislation
U.S. Food and Drug Administration
301-796-8919
andrew.tantillo@fda.hhs.gov
From: Hinton, Denise /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND
Sent: 2/20/2020 8:13:40 PM
To: Mair, Michael /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIOBF23SPDLT)/cn=Recipients/cn=f451bdad7564d7fac7eadc7961467ab-Michael.Mai
Subject: FW: HHS International SPOTREP & SLB: COVID-19 (Update #100)
Attachments: COVID-19 SLB 20Feb20 Final.pdf

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Thursday, February 20, 2020 8:07 PM
To: Goldman, David <David.Goldman@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Keller, Melanie <Melanie.Keller@fda.hhs.gov>; Thompson, Lori <Lori.Thompson@fda.hhs.gov>
Cc: FDA Commissioned Corps Affairs <FCCA@fda.hhs.gov>
Subject: FW: HHS International SPOTREP & SLB: COVID-19 (Update #100)

Today’s ASPR Senior Leader Brief on COVID-19 (2019-nCoV) attached, and HHS international SPOTREP below.

UNCLASSIFIED // FOR OFFICIAL USE ONLY

HHS International SPOTREP: COVID-19 (Update #100)

Source: Interagency

What:
• US confirmed cases: 15; Presumptive positive COVID-19 cases repatriated among Diamond Princess passengers pending U.S. confirmation testing
• 4 asymptomatic COVID-19 positive cases: 2 were transported and 2 awaiting transport from Sacramento via air ambulance to a hospital in Spokane, Washington.
• The CDC issued a Level 1 travel advisory for people traveling to Japan, which advises travelers to avoid contact with sick people and wash hands with soap and water often.
• Please see the attached Senior Leader Brief (SLB)

When: 20Feb20 1830ET

UNCLASSIFIED // FOR OFFICIAL USE ONLY

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Subject: Canceled: COVID-19 PMO Call
Attachments: COVID-19 PMO Call; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; COVID-19 HHS PMO Daily Sync Call Agenda.docx; Untitled Attachment
Location: 610F/Dial In Below
Start: 2/24/2020 11:00:00 AM
End: 2/24/2020 12:00:00 PM
Show Time As: Free
Importance: High
Recurrence: Weekly
every Monday, Tuesday, Wednesday, Thursday, and Friday from 11:00 AM to 12:00 PM
Required Attendees: Pollard, Ashton (OS/IOS); Kadlec, Robert (OS/ASPR/IO); Shuy, Bryan (OS/ASPR/IO); McGowan, Robert (Kyle) (CDC/OD/OC); Imbriale, Samuel (OS/ASPR/SIM); McCreary, Kenneth (OS/ASPR/SPPR); Perdue, Christopher (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Phillips, Sally (OS/ASPR/SPPR); Pratt, Michael (OS/ASPA); Lenihan, Keagan (FDA/OC); Mair, Michael (FDA/OC); Hinton, Denise (FDA/OC); Johnston, Darcie (HHS/IEA); Zebley, Kyle (HHS/OS/OGA); Chang, William (HHS/OGC); Truemann, Laura (HHS/IEA); Marston, Hilary (NIH/NAID); E; Kerr, Lawrence (HHS/OS/OGA); Fernandez, Jose (OS/OGA); Elvander, Erika (OS/OGA); Steven Valentine (HHS/OASH) (Steven.Valentine@hhs.gov); Schwartz, Erica (HHS/OASH); Grigsby, Garrett (HHS/OS/OGA); Moudy, Robin (OS/ASPR/SPPR); Gregg, William (Joe) (CDC/DDID/NCIRD/OD); Patel, Anita (CDC/DDID/NCIRD/OD); Dreyzehner, John (CDC/DDPHSIS/CPR/OD); McNellis, Robert (AHRQ/CEPI); Levine, Cheryl (OS/ASPR/EMMO); Kouzoukas, Demetrios
(CMS/OA); Kibunja, Julia (OS/OGA); Cochran, Norris (HHS/ASFR); Dasher, David (HHS/ASFR); Bettencourt, Alice (HHS/ASFR); Moughalian, Jen (HHS/ASFR) (Jen.Moughalian@hhs.gov); Hittle, Taylor (HHS/ASFR); Brookes, Brady (CMS/OA); Mignone, Alfred (FDA/OC); Jim Parker (HHS/IOS) (Jim.Parker@hhs.gov); Ann Agnew (HHS/IOS) (Ann.Agnew@hhs.gov); Steele, Danielle (HHS/IOS); Brooks, John (CMS/OA); Stannard, Paula (HHS/IOS); Brady, Will (HHS/IOS) (William.Brady@hhs.gov); Nick Uehlecke (HHS/IOS) (Nicholas.Uehlecke@hhs.gov); Keckler, Charles (HHS/IOS); Smith, Brad (CMS/OA); Giroir, Brett (HHS/OASH); Horska, Katerina (HHS/IOS); Arbes, Sarah (HHS/ASL) (Sarah.Arbes@hhs.gov); Baker, Michael (OS/IEA); Lincoln, Carol (OS/ASPR/EMMO); Newland, Matthew (OS/ASPR/BARDA); Oshansky, Christine (OS/ASPR/BARDA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Twomey, John K. (OS/IOS) (John.Twomey@HHS.GOV); Bradway, Courtney (HHS/ASL); Weahkee, Michael (HHS/HQ); Paden, Maris (HHS/ASL); Caitrin Shuy (HHS/ASFR) (Caitrin.Shuy@hhs.gov); Aasen, Adam (HHS/OS/OGA); Robertson, Lance (ACL); McGuffee, Tyler Ann (HHS/IOS); Monroe, Steve (CDC/DDPHSS/OLSS/OD); Donis, Ruben (OS/ASPR/BARDA); Engels, Thomas (HRSA); Cheever, Laura (HRSA); Macrae, Jim (HRSA); Morris, Tom (HRSA); Severino, Roger (HHS/OCR)
Good for me.

Would change: (b)(5)

Thank you – I changed: (b)(5) Otherwise, reads well to me!
FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika
Tweets for today’s clearance and flagging (b)(5) TY.

Abigail Capobianco, MA
Writer/Editor
Social Media Lead
Issues Management Group (IMG) Joint Information Center (JIC)
2019 Novel Coronavirus (COVID-19) IMG
Center for Tobacco Products
Office of Health Communication and Education
U.S. Food and Drug Administration
Tel: 240-402-4715
abigail.capobianco@fda.hhs.gov
http://www.fda.gov/
Good for me too – (b)(5)

Thank you!

Denise

Good for me.

Would change (b)(5)

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 21, 2020 at 11:22:37 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Would change (b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 11:04 AM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed (b)(5). Otherwise, reads well to me!

Denise
From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

From: Caliguiri, Laura
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika
Tweets for today’s clearance and flagging (b)(5)  TY.
Making sure you already weighed in along with ORA for alignment? Thanks

Keagan, Denise, Erika-
For your urgent review, the draft statement on inspections. This has been JIC and OCC cleared. I am waiting to clear one point from ORA, which is noted in the statement. Following your review, we can get to Dr. Hahn.

I’ll concurrently flag for ASPA.

Let me know if you have any questions, thanks!

Stephanie Caccomo  
Press Officer  
Office of Media Affairs  
Office of External Affairs  
U.S. Food and Drug Administration  
Desk:  301-534-1566  
Cell:  (b)(6)  
stephanie.caccomo@fda.hhs.gov
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHOF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]

Sent: 2/21/2020 2:45:00 PM

To: Caliguiri, Laura [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOHOF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d6bac66e-Laura.Calig]


Subject: FW: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Just add [b](5) this works – thanks!

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:30 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: QQ RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Erika and Denise have cleared including your note – are we good or should we wait for KL?

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:07 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 21, 2020 at 11:22:37 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>
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Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed \( (b)(5) \) Otherwise, reads well to me!

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

From: Caliguiri, Laura
Sent: Friday, February 21, 2020 10:57 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika
Tweets for today’s clearance and flagging \( (b)(5) \) TY.
(b)(5)
From: Rebello, Heidi  
[O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP  
(FYDIHOFF23SPDLTY)/CN= Recipients/CN=2834CE193CA949799E063E34A2CFA0B-HEIDI.REBEL]  
To: Caliguiri, Laura  
[O=ExchangeLabs/OU=Exchange Administrative Group  
(FYDIHOFF23SPDLTY)/cn= Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Anderson, Erika  
[O=ExchangeLabs/OU=Exchange Administrative Group  
(FYDIHOFF23SPDLTY)/cn= Recipients/cn=98606928b9a64efdfb25aba1e3573fdfe-Eranders]; Hinton, Denise  
[O=ExchangeLabs/OU=Exchange Administrative Group  
(FYDIHOFF23SPDLTY)/cn= Recipients/cn=85feba0be0694803be6030e97c7b4adb-HINTOND]; Lenihan, Keagan  
[O=ExchangeLabs/OU=Exchange Administrative Group  
(FYDIHOFF23SPDLTY)/cn= Recipients/cn=ee7320ee8c184d66bf121b0105d17d2-Keagan.Len]  
CC: Caccomo, Stephanie  
[O=ExchangeLabs/OU=Exchange Administrative Group  
(FYDIHOFF23SPDLTY)/cn= Recipients/cn=ee7320ee8c184d66bf121b0105d17d2-Stephanie.C]  
Subject: RE: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thumbs up.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
Sent: Friday, February 21, 2020 2:58 PM  
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
Subject: RE: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL or HR? Any objections?

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
Sent: Friday, February 21, 2020 2:45 PM  
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
Subject: Re: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good by me.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
Date: February 21, 2020 at 2:30:24 PM EST  
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>  
Subject: New addition FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

For clearance, new in red, official specific acknowledgement.
From: Caliguiri, Laura  
Sent: Friday, February 21, 2020 2:16 PM  
To: Heidi Rebello <Heidi.Rebello@fda.hhs.gov>; Erika Anderson <Erika.Anderson@fda.hhs.gov>  
Subject: QQ RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

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Sent: Friday, February 21, 2020 2:07 PM  
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Good for me.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
Date: February 21, 2020 at 11:22:37 AM EST  
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>  
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Would change (b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Sent: Friday, February 21, 2020 11:04 AM  
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

Thank you – I changed (b)(5). Otherwise, reads well to me!

Denise

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
Sent: Friday, February 21, 2020 10:57 AM  
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>  
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>  
Subject: RE: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

+Heidi

From: Caliguiri, Laura  
Sent: Friday, February 21, 2020 10:57 AM  
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
CC: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: FW: FOR CLEARANCE: Tweets for today- general and PHS All Hands promotion

KL Denise and Erika
Tweets for today’s clearance and flagging (b)(5)

(b)(5)

Abigail Capobianco, MA
Writer/Editor
Social Media Lead
Issues Management Group (IMG) Joint Information Center (JIC)
2019 Novel Coronavirus (COVID-19) IMG
Center for Tobacco Products
Office of Health Communication and Education
U.S. Food and Drug Administration
Tel: 240-402-4715
abigail.capobianco@fda.hhs.gov
http://www.fda.gov/
nope

KL or HR? Any objections?

Good by me.

For clearance, new in red, official specific acknowledgement.

(b)(5)
Erika and Denise have cleared including your note – are we good or should we wait for KL?

Good for me.

Would change (b)(5)

Thank you – I changed (b)(5) Otherwise, reads well to me!

Denise

+Heidi
KL Denise and Erika
Tweets for today's clearance and flagging

(b)(5)
A few edits and comments from me.

______________________________

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Friday, February 21, 2020 2:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: For urgent review: coronavirus, statement on inspections

Keagan, Denise, Erika-
For your urgent review, the draft statement on inspections. This has been JIC and OCC cleared. I am waiting to clear one point from ORA, which is noted in the statement. Following your review, we can get to Dr. Hahn.

I’ll concurrently flag for ASPA.

Let me know if you have any questions, thanks!

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccamo@fda.hhs.gov
Today's Accomplishments
- COS note to JIC members clarifying expectations and commitment (going later this PM)
- Dr. Hahn all-hands email to FDA employees (going later this PM)
- FDA Statement on Inspections – going through final clearance (going later this PM)
- Op-Ed on fraud through clearance
- Tweets:
  - NIAID news on remdesivir trial/cross-posting
  - FDA Statement on inspections
  - Dr. Hahn at PHS All-Hands w/photos
- Cleared 1st set of comprehensive FDA talkers on COVID-19
- Commissioner Chat filmed today

Future Items

(b)(5)
Thanks! I've incorporated all your feedback into this version. I'll clean up and move along. Thank you!

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, February 21, 2020 4:13 PM
To: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: For urgent review: coronavirus, statement on inspections

Edits

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Friday, February 21, 2020 3:56 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: For urgent review: coronavirus, statement on inspections

Thank you both! Keagan, ok with you? I am happy to clean up and get into Dr. Hahn’s HW over the weekend.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 21, 2020 3:49 PM
To: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>
Subject: RE: For urgent review: coronavirus, statement on inspections

Me too – thank you!

Denise
A few edits and comments from me.

Keagan, Denise, Erika-
For your urgent review, the draft statement on inspections. This has been JIC and OCC cleared. I am waiting to clear one point from ORA, which is noted in the statement. Following your review, we can get to Dr. Hahn.

I’ll concurrently flag for ASPA.

Let me know if you have any questions, thanks!

Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov
FYI - CDC Key Points on COVID-19 for today are attached. A good overall brief, succinctly presented.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: (b)(6)
Thanks Laura and Stephanie. It’s well after 8am but I’m comfortable with the response you provided below, as they are from cleared talking points.

Best,

Denise
FYSA SC has run this by ASPA and working through CDER/JIC. She will respond closer to the 8am deadline.

(b)(5)
Hi all—

Early flag on an axios story on an apparent list we compiled on 150 drugs at risk for shortage if outbreak continues. It’s on hold for right now. I’m tracking down info and will keep you posted. Thx!

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(5)
stephanie.caccomo@fda.hhs.gov

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Hey folks—

(b)(5)

Stephanie Caccamo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(5)
stephanie.caccomo@fda.hhs.gov

---

From: Finnen, April <April.Finnen@fda.hhs.gov>
Date: February 22, 2020 at 6:52:43 PM EST
To: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: URGENT: Request for comment — urgent
Subject: RE: Request for comment — urgent

Here's what we have on this from the master talking points (I am not sure if these are OCC-cleared yet, but they went to OCC on Friday, and were pulled from cleared TPs and other cleared docs we have been using). Brooke – OK w/you? Michael/Stephanie – defer to you on how much of this to send to reporter.

(b)(5)
Hi all,

Lorrie

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: February 22, 2020 at 5:49:40 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>
Subject: Re: Request for comment — urgent

Thanks—apologies for any redundancies, but adding CDER shortage sme’s just in case not on the jic list given the time urgency.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: February 22, 2020 at 5:46:54 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>
Subject: Fwd: Request for comment — urgent

Hi JIC team,

Please see the inquiry below.

Thanks,

Michael

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

From: Caitlin Owens <_b>(6)>
Date: February 22, 2020 at 5:44:50 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Request for comment — urgent
Hi Michael, I’ve heard the FDA has a list of about 150 drugs that are at risk of shortage if the coronavirus situation gets worse in China. It includes antibiotics, generics and some single source branded drugs. I plan to write tonight, so if you could respond with input/comment ASAP, that’d be very helpful.

I'm aiming to publish by 6:45 or so, but I know that's not much time so can be flexible. Thanks!

--
Caitlin Owens
Axios
Reporter
(c)(b)(6)
Thanks Denise! SC sent the link around.

Thanks Laura and Stephanie. It’s well after 8am but I’m comfortable with the response you provided below, as they are from cleared talking points.

Best,

Denise
Hi all—
Early flag on an Axios story on an apparent list we compiled on 150 drugs at risk for shortage if outbreak continues. It’s on hold for right now. I’m tracking down info and will keep you posted. Thx!

Stephanie Caccamo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: [____(b)(6)____]
stephanie.caccamo@fda.hhs.gov
Hey folks—

Stephanie Caccamo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov

From: Finnen, April <April.Finnen@fda.hhs.gov>
Date: February 22, 2020 at 6:52:43 PM EST
To: McNeil, Lorrie <Lorrie.McNeil@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Request for comment — urgent

Here’s what we have on this from the master talking points (I am not sure if these are OCC-cleared yet, but they went to OCC on Friday, and were pulled from cleared TPs and other cleared docs we have been using). Brooke – OK w/you? Michael/Stephanie – defer to you on how much of this to send to reporter.
Hi all {(b)(4) (b)(5)}

Lorrie
Thanks—apologies for any redundancies, but adding CDER shortage sme’s just in case not on the jic list given the time urgency.

---

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Date: February 22, 2020 at 5:46:54 PM EST
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: Fwd: Request for comment — urgent

Hi JIC team,

Please see the inquiry below.

Thanks,

Michael

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

---

From: Caitlin Owens <cb67bb0a8603687c6574c5164d975877>
Date: February 22, 2020 at 5:44:50 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Request for comment — urgent

Hi Michael, I’ve heard the FDA has a list of about 150 drugs that are at risk of shortage if the coronavirus situation gets worse in China. It includes antibiotics, generics and some single source branded drugs. I plan to write tonight, so if you could respond with input/comment ASAP, that’d be very helpful.

I’m aiming to publish by 6:45 or so, but I know that’s not much time so can be flexible. Thanks!

--

Caitlin Owens
Axios
Reporter
c(b)(6)
From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Date: February 23, 2020 at 11:50:28 PM EST
To: Goldman, David <David.Goldman@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>
Cc: FDA Commissioned Corps Affairs <FCCA@fda.hhs.gov>, Mahmud, Nasser <Nasser.Mahmud@fda.hhs.gov>

WHO Situation Report attached.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: [____(b)(6)_____]
From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, February 24, 2020 11:38 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: For IMG Review

PRE-DECISIONAL, CONFIDENTIAL

Hi Michael and Tom –

Attached are close hold memos coming to us from HHS / WH.

By 12pm tomorrow, can IMG provide initial thoughts on these 3 sets of recommendations related to remdesivir, needles, and face masks? It would be most helpful to know where FDA has equities and if there are any key considerations we can communicate to HHS.

Please let me know if you have questions. Thanks in advance for your time in between everything else on your schedules.

Anand
Thanks to the Lord!

From: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Sent: Monday, February 24, 2020 11:58 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Hoping for the best!

Thanks Denise.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, February 24, 2020 11:54 AM
To: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Subject: Hoping for the best!

Oh my goodness —

From: Rawlings, Kimberly <Kimberly.Rawlings@fda.hhs.gov>
Sent: Monday, February 24, 2020 7:15 AM
To: Choe, Lena <lena.Choe@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: URGENT: Request for comment — urgent

Thanks for being in the loop yesterday evening.

I'm trying to determine what's been shared for my awareness.

Kim

From: Choe, Lena <lena.Choe@fda.hhs.gov>
Date: February 22, 2020 at 8:13:57 PM EST
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
We are not aware of an FDA list of drugs at risk of shortage. I would like to share that there is a list of essential meds from a non-FDA source that has been circulating.

Vizient Identifies Essential Medications in Hospitals and Highlights Fragility of the Supply Chain

Vizient's List of Essential medications

CDER Comms is fine with this response (from our most recent statement) unless there are any other concerns.

Thanks,
Lena
From: Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>
Sent: Saturday, February 22, 2020 7:25 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>; Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>; CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Re: URGENT: Request for comment — urgent

I will let or comms folks check in, but from my conversations on Thursday and Friday in the Center this doesn’t sound right. This may be a reference to checking in on the facilities in China or looking at essential medicines, but I don’t believe this is accurate the way it is stated here.

---

From: "Courtney, Brooke" <Brooke.Courtney@fda.hhs.gov>
Sent: Saturday, February 22, 2020 7:10 PM
To: "Caccamo, Stephanie" <Stephanie.Caccamo@fda.hhs.gov>,"Finnen, April" <April.Finnen@fda.hhs.gov>,"McNeill, Lorrie" <Lorrie.McNeill@fda.hhs.gov>,"Felberbaum, Michael" <Michael.Felberbaum@fda.hhs.gov>,2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>,"Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Cc: "Patel, Paras M" <Paras.Patel@fda.hhs.gov>,"Jensen, Valerie E" <Valerie.Jensen@fda.hhs.gov>,CDER-ER-OPS <CDEREROPS@fda.hhs.gov>,"Hinton, Denise" <Denise.Hinton@fda.hhs.gov>,"Mair, Michael" <Michael.Mair@fda.hhs.gov>
Subject: Re: URGENT: Request for comment — urgent

---

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Date: February 22, 2020 at 7:01:15 PM EST
To: Finnen, April <April.Finnen@fda.hhs.gov>, McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Cc: Patel, Paras M <Paras.Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie.Jensen@fda.hhs.gov>, CDER-ER-OPS <CDEREROPS@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: URGENT: Request for comment — urgent

Hey folks—

(b)(5)
From: Finnen, April <April.Finnen@fda.hhs.gov>
Date: February 22, 2020 at 6:52:43 PM EST
To: McNeill, Lorrie <Lorrie McNeill@fda.hhs.gov>, Courtney, Brooke <Brooke Courtney@fda.hhs.gov>, Felberbaum, Michael <Michael Felberbaum@fda.hhs.gov>, 2019-nCoV FDA IMG JIC <2019-nCoV FDA IMG JIC@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie Caccamo@fda.hhs.gov>, Patel, Paras M <Paras Patel@fda.hhs.gov>, Jensen, Valerie E <Valerie Jensen@fda.hhs.gov>, CDER-ER-OPS <CDER-ER-OPS@fda.hhs.gov>
Subject: RE: Request for comment — urgent

Here's what we have on this from the master talking points (I am not sure if these are OCC-cleared yet, but they went to OCC on Friday, and were pulled from cleared TPs and other cleared docs we have been using). Brooke - OK w/you? Michael/Stephanie — defer to you on how much of this to send to reporter.
Hi all -

(b)(4)  (b)(5)

Lorrie

Hi JIC team,

Please see the inquiry below.

Thanks,

Michael

Michael Felberbaum
Senior Advisor
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel: 240-402-9548 / Cell (b)(6)  
michael.felberbaum@fda.hhs.gov
From: Caitlin Owens
Date: February 22, 2020 at 5:44:50 PM EST
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Request for comment — urgent

Hi Michael, I’ve heard the FDA has a list of about 150 drugs that are at risk of shortage if the coronavirus situation gets worse in China. It includes antibiotics, generics and some single source branded drugs. I plan to write tonight, so if you could respond with input/comment ASAP, that’d be very helpful.

I’m aiming to publish by 6:45 or so, but I know that’s not much time so can be flexible. Thanks!

--

Caitlin Owens
Axios
Reporter


Hi - Can you provide more detail on what is wanted so we can provide more/better info?

And, what can the JIC proactively communicate about – it can be updates or educate the public on FDA's roles in each Center/ORA....

The JIC is working proactive comms every day – is something missing?
Hi Laura,

FDA (including CDRH) comments/edits are attached. We defer to CDC and ASPR on accuracy of the statistics. If you have any questions, just let us know.

Thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) 301-443-7884 (cell)
brooke.courtney@fda.hhs.gov

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Sent: Tuesday, February 25, 2020 9:59 AM
To: Patel, Anita (CDC) <bop1@cdc.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Phillips, Sally (OS) <Sally.Philips@hhs.gov>; Messonnier, Nancy E (CDC) <nar5@cdc.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>
Cc: Seiler, Brittney J (OS) <Brittney.Seiler@hhs.gov>; Christl, Thomas (OS) <Thomas.Christl@hhs.gov>
Subject: RE: Problem statement- RPDs

All-

Please see attached the draft statement. (b)(5)
Please distribute within your agencies for comment/revisions and let me know if you think you can get feedback to my team by 3pm.

Thanks-

Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov.gov
Desk: 202-260-0666
Cell: (b)(5)

From: Wolf, Laura (OS/ASPR/SIIM)
Sent: Tuesday, February 25, 2020 7:19 AM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bopl@cdc.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>; Phillips, Sally (OS/ASPR/SPPR) <SallyPhillips@hhs.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>
Subject: RE: Problem statement- RPDs

FYSA- had significant technology challenges overnight, so wrapping up the draft now. You’ll have it shortly.

Laura

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

From: Wolf, Laura (OS/ASPR/SIIM)
Sent: Monday, February 24, 2020 5:28 PM
To: Patel, Anita (CDC/DDID/NCIRD/OD) <bopl@cdc.gov>; Courtney, Brooke (FDA/OC) <Brooke.Courtney@fda.hhs.gov>; Adams, Steven A. (CDC/SNS/DSNS) <saa1@cdc.gov>; Phillips, Sally (OS/ASPR/SPPR) <SallyPhillips@hhs.gov>; Messonnier, Nancy (CDC/DDID/NCIRD/OD) <nar5@cdc.gov>; Falcon, Jessica (OS/ASPR/SIIM) <Jessica.Falcon@hhs.gov>; DeBord, Kristin (OS/ASPR/SPPR) <Kristin.DeBord@hhs.gov>
Subject: Problem statement- RPDs

Colleagues-

I will pull together tonight a
Laura

Laura Kwinn Wolf, Ph.D.
Director, Division of Critical Infrastructure Protection
HHS/ASPR
Unclassified: Laura.wolf@hhs.gov
HSDN: Laura.wolf@dhs.gov.gov
Desk: 202-260-0666
Cell: (b)(6)
Subject: SARS-CoV-2
Location: EEOB SMS Large- IN PERSON

Start: 2/26/2020 11:00:00 AM
End: 2/26/2020 12:30:00 PM
Show Time As: Busy

Recurrence: (none)

Dear Colleagues,

As discussed today, SAP Ruggiero will convene an in person on February 26, 2020, from 11:00 A.M.-12:30 PM.

Participants are expected to attend in person. With exception of CDC Atlanta, NIAD and FDA there will be no additional SVTC connections.

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

Please use the WAVES link to register for attendance.

Best Regards,

Phil
Dear Colleagues,

As discussed today, SAP Ruggiero will convene an in person meeting on February 26, 2020, from 11:00 A.M. - 12:30 PM. Participants are expected to attend in person. With exception of CDC Atlanta, NIAD and FDA there will be no additional SVTC connections.

Accordingly, individuals attending this meeting should be prepared to present their D/A content and must have the authority to speak on the behalf of their organization.

Please use the WAVES link to register for attendance.

Best Regards,

Phil
From: Nabakowski, Andrei [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=8C8BCECC310C4E45A5012D47D40886E1-NABAKOWSKIA]

Sent: 2/25/2020 7:32:03 PM


Subject: FW: HHS International SPOTREP: COVID-19 (Update #111)

Attachments: COVID-19 SLB 25Feb20 FINAL.pdf

FYI- attached is today’s ASPR Senior Leadership Brief for COVID-19 and below is an HHS SPOTREP.

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HHS International SPOTREP: COVID-19 (Update #111)

Source: Interagency

What:
- Current global cases are 80,116 and 2,697 global deaths
- Miramar NAS will be closing down after today and being returned to DoD; One additional positive case was transferred from Lackland AFB to UNMC
- NIAID clinical trial began Feb 21 at UNMC to evaluate the safety and efficacy of Remdesivir as a therapeutic agent
- For further information, please see the attached Senior Leader Brief (SLB)
From: Hinton, Denise /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND
Sent: 2/25/2020 8:10:09 PM
To: Goldman, David /o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7a9c6c3e900b4771876c53fa24c1172b-David.Goldm]; Tarver, Darian B. /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50bc9a244d944d62aa1660f40055d460-Darian.Tarv]; Nabakowski, Andrei [Andrei.Nabakowski@fda.hhs.gov]; Anderson, Randy /o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34b8eb6207ba48258beec293c71f4a93-ANDERSONRA
Subject: FYSA: FDA 2019-nCOV SITREP - 25 Feb 2020

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 5:03 PM
Subject: FDA 2019-nCOV SITREP - 25 Feb 2020

Hi,

Attached for your situational awareness is the 25 February FDA 2019-nCoV SITREP.

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

Many thanks for your continued support. -Michael
Thanks for the quick response, Charlotte. Based on this morning’s call, sounds like FDA (and other OPDIVs, I’m sure) are under the gun to turn this around rapidly and concisely.

Winona Cason  
Associate Director for Management/Executive Officer  
National Center for Toxicological Research, Jefferson, AR  
Office of Management  
U.S. Food and Drug Administration  
Tel: 870-543-7351  
winona.cason@fda.hhs.gov

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>  
Sent: Wednesday, February 26, 2020 7:54 AM  
To: Cason, Winona <Winona.Cason@fda.hhs.gov>  
Cc: Willis, Ken <Ken.Willis@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>  
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

FYI....

From: Ashcraft, Charlotte  
Sent: Wednesday, February 26, 2020 7:54 AM  
To: Willis, Ken <Ken.Willis@fda.hhs.gov>  
Cc: FDA Budget Formulation - NCTR <FDABudgetFormulation-NCTR@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>; Cason, Winona <Winona.Cason@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>  
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Good Morning Ken,  
The spreadsheet is locked by another user, so I’ve attached our information here only.
If you have any questions, please let me know.

Thanks
Charlotte

---

From: Willis, Ken <Ken.Willis@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:39 PM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Cc: FDA Budget Formulation - NCTR <FDABudgetFormulation-NCTR@fda.hhs.gov>; Tsai, Chen-Tin <Chen-Tin.Tsai@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Thanks Charlotte. Can you please also let us know

Ken D. Willis, MBA
Lead Budget Analyst
U.S. Food and Drug Administration (FDA)
Office of Budget (OB)
Division of Budget Formulation
4041 Powder Mill Road
Office 72115A
Phone: 301-796-4372
Email: Ken.Willis@fda.hhs.gov

---

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 5:28 PM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>
Cc: FDA Budget Formulation - NCTR <FDABudgetFormulation-NCTR@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

NCTR information is completed.

Thanks,
Charlotte

“A lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good just because it’s accepted by a majority.” Booker T. Washington

---

From: Willis, Ken <Ken.Willis@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 4:20 PM
To: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category
Thanks for letting me know. I am out of it now.

Ken D. Willis, MBA
Lead Budget Analyst
U.S. Food and Drug Administration (FDA)
Office of Budget (OB)
Division of Budget Formulation
4041 Powder Mill Road
Office 72115A
Phone: 301-796-4372
Email: Ken.Willis@fda.hhs.gov

OFFICE OF FINANCE BUDGET
AND ACQUISITIONS
#OFBAWhereTheStewardshipHappens

From: Ashcraft, Charlotte <Charlotte.Ashcraft@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 5:20 PM
To: Willis, Ken <Ken.Willis@fda.hhs.gov>
Subject: RE: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category

Hi Ken,
You have the file locked. 😊 Can you let me know when it is available?

Thanks,
Charlotte

“A lie doesn’t become truth, wrong doesn’t become right and evil doesn’t become good just because it’s accepted by a majority.” Booker T. Washington

From: FDA Office of Budget <FDAOfficeofBudget@fda.hhs.gov>
Sent: Tuesday, February 25, 2020 3:44 PM
To: FDA Budget Formulation Contacts <FDABudgetFormulationContacts@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Green, Jamie <Jamie.Green@fda.hhs.gov>; Enoch, Bobby <Bobby.Enoch@fda.hhs.gov>; Yates, Connie <Connie.Yates@fda.hhs.gov>; Buchanan, Noni <Noni.Buchanan@fda.hhs.gov>; Tan, William <William.Tan@fda.hhs.gov>; Akparewa, Amy <Amy.Akpereawa@fda.hhs.gov>; Roosen, Suzanne <Suzanne.Roosen@fda.hhs.gov>
Cc: FDA Budget Formulation-OB <FDABudgetFormulationOB@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Wong, Eric <Eric.Wong@fda.hhs.gov>; Matthews-Ockiya, Swynice <Swynice.Matthews-Ockiya@fda.hhs.gov>; Grant, Leonard D <Leonard.Grant@fda.hhs.gov>; FDA Executive Officers <ExecOfficer@fda.hhs.gov>
Subject: DC-20-06-F: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category
DATE: February 25, 2020
DATA CALL #: 20-06-F
MEMO FOR: FDA Budget Formulation Community
FROM: Bill Tootle
Director, Office of Budget
SUBJECT: FY 2020 to FY 2024 Coronavirus Resource Estimates by Category
Due Dates: 10:30 am Wednesday, February 26, 2020
Affected Organizations: All FDA Centers, ORA and HQ Offices

Purpose: To breakout the estimates of FDA's total anticipated costs related to the Coronavirus outbreak among four priorities categories identified by FDA leadership to ensure FDA can provide technical assistance to Congress on our anticipated needs, both in the short-term (FY 2020), and in the outyears (FY 2021 – FY 2024).

Center/Office Action Required: Update the table in SharePoint to identify the estimated costs and timing (for the appropriate fiscal year(s)) of the following:

In the description section, please distinguish the activities that will be performed in FY 2020 from those anticipated to be performed in the outyears (FY 2021 – FY 2024).

OB has provided an updated spreadsheet and SharePoint location to collect this information. This data call is separate from the data call regarding the

(b)(5)

(b)(5) It is also different from the weekly data collection that is due each Wednesday. Please use the FY 2020 to FY 2024 Coronavirus Cost Estimates by Category spreadsheet via SharePoint to enter your center or office’s information.

In the file, you will notice several rows under each center/office. This is for you to break out the funding among the high priority categories identified above. You will need to provide a short description of the activities you would carry out under each priority category. You will also notice a fifth row labeled “Other.” Every effort should be made to capture your costs in one of the four categories of activities identified in the bullets above. The Other category is intended to give you a place to identify any major activities not captured in the four primary categories.

Insert your Center or Office’s respective numbers, and save the FY 2020 to FY 2024 Coronavirus Cost Estimates by Category spreadsheet under the same file name. Please close out of the Excel file after saving your center or office’s updates. Do not upload a new version of the file as that will overwrite any changes made by other centers and offices.

Fill out only columns and cells that are highlighted in yellow and only the rows that correspond to your Center or Office. Do not alter or delete data pertaining to another Center or add rows to the spreadsheet.
Background: The seriousness of the coronavirus outbreak makes this a high priority activity so we want to be able to provide Congress with our best estimates of our anticipated level of effort to address our responsibilities. Each center/office will need to provide their estimated costs to OB by 10:30 am Wednesday (2/26/2020).

DBFPA Contact: Please contact Bill Tootle, Eric Wong, Ken Willis, CT Tsai, or your DBF Analyst with any questions or concerns. Updated contact information can be found on the Office of Budget - Formulation SharePoint Home Page.
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 2/26/2020 10:35:08 AM
To: Mair, Michael [o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f451bda7f564a7facf7eadc7961467ab-Michael.Mai]
Subject: FYI: For review this morning: statement on supply chain
Attachments: Supply chain draft statement_2.26.20 occ cleared.docx

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 9:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: For review this morning: statement on supply chain

Keagan, Denise, Erika-

Attached is a draft statement, to issue from Dr. Hahn, on the status of the supply chain across FDA regulated products. (b)(5) we think it will be very helpful to reporters who have been individually pinging for this same information.

(b)(5)

This is JIC and OCC cleared. Once you clear, I will send to HHS for HHS/WH review and put in Dr. Hahn HW. Fingers crossed we could issue tomorrow!

Thanks!
Stephanie Caccamo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6) stephanie.caccamo@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

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FDA-OSJI-FOIA-2020-3541_00001597
From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 9:39 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: For review this morning: statement on supply chain

Keagan, Denise, Erika-

Attached is a draft statement to issue from Dr. Hahn on the status of the supply chain across FDA regulated products. We think it will be very helpful to reporters who have been individually pinging for this same information.

(b)(5)

This is JIC and OCC cleared. Once you clear, I will send to HHS for HHS/WH review and put in Dr. Hahn HW. Fingers crossed we could issue tomorrow!

Thanks!

Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov
Get back for Navarro and something the HHS team might want to be inserted in PCC process.

Good Afternoon Keagan,

I am attaching the CDER-cleared response to Dr. Navarro’s request for information on the supply of products on the “List of Essential Medications for Severe CVD Infection.” I’m also attaching a suggested cover memo. Please let me know if you have any questions or need additional information.

Thank you,
Jessica

Jessica Bernstein, MPH
Office of Executive Programs, CDER
Office phone: 240-402-0524
All,

For your awareness — Attached is the draft issues paper on N95 respirators I provided an overview of during this morning’s meeting. It has gone to the WH for coordination in the COVID-19 Supply Chain Coordination Working Group for their input on potential courses of action. This is a draft document that was coordinated through ASPR, CDC, and FDA.

Best,
Kristin

-----Original Appointment-----
From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Sent: Friday, February 21, 2020 11:15 AM
To: Mango, Paul (HHS/IOS); Pollard, Ashton (OS/IOS); Kadlec, Robert (OS/ASPR/IO); Shuy, Bryan (OS/ASPR/IO); McGowan, Robert (Kyle) (CDC/OD/OCS); Imbriale, Samuel (OS/ASPR/SIIM); Mccreary, Kenneth (OS/ASPR/SPPR); Perdue, Christopher (OS/ASPR/SPPR); DeBord, Kristin (OS/ASPR/SPPR); Phillips, Sally (OS/ASPR/SPPR); Pratt, Michael (OS/ASPA);
Subject: COVID-19 PMO Call
When: Wednesday, February 26, 2020 10:00 AM-10:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: 610F/Dial In Below

(b)(6)
FYI- attached is today’s COVID-19 SITREP, already sent to the AEG (so RADM Hinton has it, but cc’ing her again here for awareness).

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell (b)(6) FCCA.

From: Measer, Gregory <Gregory.Measer@fda.hhs.gov>
Sent: Wednesday, February 26, 2020 5:09 PM
To: 2019-nCoV FDA IMG <2019-nCoVFDAIMG@fda.hhs.gov>
Subject: FW: FDA 2019-nCoV SITREP - 26 Feb 2020

FYI -- the attached 26 Feb SITREP has been posted to SharePoint. Thanks.

Best,
Greg
Hi,

Attached for your situational awareness is the 26 February FDA 2019-nCoV SITREP.

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

Many thanks for your continued support. -Michael
Okay

I will ask around.

(b)(5)

(b)(5)

(b)(5)

Hello Denise,

Hope all is well with you. I wanted to reach out to you regarding the COVID-19 virus and the potential for the Emulate Organs-on-Chip technology to be applied to answer key questions related to the emerging novel coronavirus outbreak.

We have been communicating with our key contacts (b)(4) Based on their feedback and the questions being raised about the virus. We came up with 3 main ideas on how the Emulate platform could potentially be useful for the ongoing outbreak in two main ways:

(b)(4)
3. Efficacy and safety testing of potential antiviral therapeutic candidates

Here are links to some of our publications demonstrating the potential to use Organs-on-Chips for infectious disease:

https://www.biorxiv.org/search/lung%2Bchip

https://www.biorxiv.org/content/10.1101/2020.02.03.931170v1


We are currently putting together a one-page document to capture this.

Do you think the FDA would like to be involved in this effort in some way? Would be great to discuss further and get your insights.

This may be very short notice but I plan to be in DC on Thursday - we could explore meeting in person if schedule aligns but totally understand that you must be super busy right now.

Look forward to hearing from you.

Best wishes,
Geraldine.
transmitting software viruses, but we advise you to carry out your own virus checks on any attachment to this message. We cannot accept liability for any loss or damage caused by software viruses. The information contained in this communication may be confidential and may be subject to the attorney-client privilege. If you are the intended recipient and you do not wish to receive similar electronic messages from us in the future then please respond to the sender to this effect.
From: Mair, Michael [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHF23SPDLT)/CN=RECIPIENTS/CN=F4S11BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 2/27/2020 3:09:54 PM
To: Hinton, Denise [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: TPs
Attachments: TPs_27 FEB 2020.docx

Hows this
CDC and FDA colleagues-

Our colleagues at OSHA have asked for review of a draft document that enables enforcement discretion for their staff in the field regarding annual fit-testing requirements so long as certain criteria are met. Also see questions below, if there is any feedback on triggers. Please send comments back to PDAS Sweatt and Mr. Brown from OSHA.

Laura

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

From: Wolf, Laura (OS/ASPR/SIIM) <Laura.Wolf@hhs.gov>
Date: February 27, 2020 at 4:43:02 PM EST
To: Patel, Anita (CDC) <bopl@cdc.gov>, Pillai, Satish K (CDC) <vig8@cdc.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ricci, Linda J <Linda.Ricci@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
Cc: Sweatt.Loren.E@dol.gov <Sweatt.Loren.E@dol.gov>, Brown, Christopher (DOL.GOV) <brown.christopher.k@dol.gov>
Subject: FW: Fit-testing checklist development

CDC and FDA colleagues-

Our colleagues at OSHA have asked for review of a draft document that enables enforcement discretion for their staff in the field regarding annual fit-testing requirements so long as certain criteria are met. Also see questions below, if there is any feedback on triggers. Please send comments back to PDAS Sweatt and Mr. Brown from OSHA.

Laura
Attached please find a draft, deliberative document relating to the issue of annual fit testing. OSHA looks forward to comment from HHS/ASPR. The question of timing the release of the document remains open. Is HHS going to make a declaration of a shortage, or state concern regarding the current supply or supply chain issues? Looking forward to further discussion on this. And, apologies for the delay on our end. I am always overly optimistic about the clearance process. Thanks.

Loren
Thanks – no further comments from me.

Denise
Today's ASPR SLB attached and HHS SPOTREP info below.

**Senior Leadership Brief pages 1-7**

**CDC Situation Report pages 8-13**

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**HHS International SPOTREP: COVID-19 (Update #117)**

**Source:** Interagency

**What:**
- Current global cases are 82,066 and 2,800 global deaths.
- CDC submitted updated guidance on optimizing the use of N95 respirators in healthcare settings to include use of stockpiled N95 respirators beyond the manufacturer-intended shelf life and a check sheet to help healthcare facilities prioritize the order of implementation.
- On February 26, CDC confirmed an infection with the virus that causes COVID-19 in a person, within the U.S., who reportedly did not have relevant travel history or exposure to another COVID-19 patient.
- President Trump announced Vice President Mike Pence will oversee National Level COVID-19 Task Force.

For further information, please see the attached Senior Leader Brief (SLB), which includes the 27Feb20 CDC SITREP for Novel Coronavirus.

**When:** 27Feb20 1858ET

**UNCLASSIFIED // FOR OFFICIAL USE ONLY**
Dear Denise,

That sounds perfect. Thank you for your prompt response.

Kind regards,
Diana

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, February 27, 2020 6:50 PM
To: Diana Brainard <Diana.Brainard@gilead.com>
Subject: [EXTERNAL] RE: connection with Gilead re COVID-19

Dear Diana,

Thank you for your email and offer to be of further assistance.

I appreciate Gilead’s work with the Office of Infectious Disease and am hopeful remdesivir will prove to be an effective treatment for COVID-19.

I will contact you with questions as needed.

Very respectfully,

Denise

RADM Denise M. Hinton
Chief Scientist
Office of the Chief Scientist
Office of the Commissioner
U.S. Food and Drug Administration
U.S. Public Health Service
(301) 796-1090 (o)

From: Diana Brainard <Diana.Brainard@gilead.com>
Sent: Thursday, February 27, 2020 9:12 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: connection with Gilead re COVID-19

Dear Denise,
I’m reaching out to you at the suggestion of Rachel Sherman. I lead the virology group at Gilead and, as such, have been running our remdesivir program and response to the COVID-19 outbreak within Gilead.

Rachel shared that the Emerging Threats group reports to you, and I didn’t know if we could be of assistance in any way. We are working very effectively with the Antiviral Division in terms of our clinical development plans.

I’d be happy to jump on the phone for an introductory call, or feel free to reach out should any questions on your part arise.

Kind regards,
Diana

Diana M Brainard, MD
Senior Vice President
Virology Therapeutic Area
Gilead Sciences, Inc
Tel: 650-522-4761
Good morning Denise,

Attached are the TP’s for the DLG that have been modified from a briefing Dr. Hahn is giving this morning. I don’t know the DLG audience, but of course, please feel free to adjust the TP’s to best suite the time and audience.

Also attached are master TP’s for you to review in case ransom questions come up (not curated, just pulled from SP site). Please let me know if you have any questions ahead of time, and I’ll see you this afternoon.

Thanks,
Prakash

No problem – I see all over the news about reported drug shortages.

Thank you!

Hi Denise,

We’ll pulling together the TP’s and I’ll send something tonight, or early tomorrow. There’s a lot of last minute edits due to all the activity tonight! For the afternoon briefing, you don’t need to give comments, and I may need to bring the QA at the last minute.

Thanks,
Prakash
May I have a copy of the most current remarks/talking points when you have an opportunity? I will be participating in the Disaster Leadership Group (DLG) meeting tomorrow morning at 1045 for Dr. Hahn. The purpose of this DLG is to gather HHS and interagency senior leaders to provide Departmental updates on COVID-19 activities\(\text{(b)(5)}\). Then I have the Bicameral Staff Briefing in the afternoon with you.

Thanks,

Denise
24/7 and is it ever evolving!

You're welcome. I figured you'd be involved with COVID. Have a great weekend!

Thank you for sending this!

FYI

Research Outlines How Drug in Clinical Trial for Coronavirus Works

Feb 28, 2020 | By Molly Campbell, Science Writer, Technology Networks
A new study published in the *Journal of Biological Chemistry* outlines how an antiviral drug that is currently being tested in patients with the novel coronavirus (COVID-19), remdesivir, works.

Antiviral drugs are not yet approved for managing human coronaviruses, which is creating a wealth of challenges in the current efforts to contain the outbreak of COVID-19 which is caused by the SARS-CoV-2 virus. In order to survive and replicate, viruses must possess molecular machinery that can generate copies of their genetic material.
Are We Heading for a Coronavirus Pandemic?

READ MORE

Coronaviruses are known to replicate their genetic material via an enzyme called RNA-dependent RNA polymerase. Remdesivir, developed by Gilead Sciences, is a nucleotide analogue that was originally created for the treatment of the Ebola virus.

Studies in cell culture and animal models have demonstrated that the drug has a wide range of antiviral effects against a number of viruses, including coronaviruses. In this study, scientists used polymerase enzymes from the coronavirus that causes Middle East Respiratory Syndrome (MERS) to further explore remdesivir's mechanism of action.

The work was led by Matthias Götte, a virologist and professor at the University of Alberta, Edmonton. He said: "It hasn't been easy to work with these viral polymerases". Due to this factor, previous work exploring the drugs function has been slow.

Götte and team discovered that the polymerase enzymes are able to incorporate remdesivir into their structure as it resembles an RNA building block, thereby "confusing" the enzyme. Upon this incorporation, the enzyme can no longer add more RNA subunits, halting the replication of the virus' genetic material.
Why does this happen? The scientists suggest that the RNA containing remdesivir is a strange shape and therefore doesn't fit into the enzyme. To prove this hypothesis, they would need to obtain structural data on the enzyme and the synthesized RNA.

Remdesivir has not been approved as a drug anywhere in the world. According to Gilead, results from a clinical trial with COVID-19 patients in China are expected in April.

Randy, thanks for this suggestion. My only concern is in (b)(5).

SUGGESTION: If the decision is to (b)(5)

Best Regards,
Randy L. Anderson, M.S., R.Ph, GWCPM
FDA Commissioned Corps Senior Advisor
That makes sense to me. But let me defer to CAPT Nabakowski regarding the feasibility of implementing that suggestion.

From: Goldman, David <David.Goldman@fda.hhs.gov>
Sent: Friday, February 28, 2020 1:15 PM
To: Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>

Good afternoon Executive Officers,

Below you will find information on FDA officers rostered/deployed/demobilized associated with the Coronavirus response, reflecting changes received to date. If you have questions regarding the numbers below, please do not hesitate to contact your Center/Office Commissioned Corps Liaison. Please know that we are available to work collaboratively with you and your Center/Office Commissioned Corps Liaison to address any questions you might have.

Thanks!
Darian

- Total of 143 (+11) FDA officers have been involved in COVID-19 (2019-nCoV) response.
  - 66 (-4) officers are deployed* (per scheduled departure date; departure not confirmed).
  - 21 (+11) officers are rostered* to deploy.
  - 56 (+4) officers confirmed demobilized.

*Listed “STATUS” is generally determined by scheduled dates of deployment. “START_DATE” in past or present classifies “Deployed” status, and “START_DATE” in future classifies “Rostered” status. This means that some officers listed as “deployed” could potentially have had their travel delayed, and still pending. These dates and status can change swiftly depending on operational decisions, and we will seek to reconcile ahead. Please note that we continue to seek reconciled lists from RDB, but we do not receive updates beyond initial deployment notifications apart from some requests for extension (and we do not receive all of those). This is an important point - some of the officers listed as “deployed” may not have received travel orders from ASPR or through RDB. For demobilized status, FCCA’s approach is to seek confirmation that an officer has actually returned before any change in a listed “deployed” status to “demobilized”.

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Darian Tarver, CAPT, USPHS  
Director  
FDA Commissioned Corps  
Office of Operations  
U.S. Food and Drug Administration  

darian.tarver@fda.hhs.gov
From: Rebello, Heidi [O=EXCHANGE LABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBE]  
Sent: 2/28/2020 4:01:47 PM  
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets  

See edits in red and in yellow below.

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>  
Sent: Friday, February 28, 2020 3:55 PM  
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Subject: FW: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets  

For your approval OCC has cleared the following tweets on the supply chain statement.

**Supply Chain Tweets**

@SteveFDA Account

**Individual tweets--- To be spread out**

3/1/20

2. See my update on how @US_FDA is monitoring the supply chain of FDA-regulated products and working to mitigate shortages during the #coronavirus outbreak: [LINK TO SUPPLY CHAIN STATEMENT]

2/29/20

**Thread 1—Drug shortage:**

2. The shortage is due to an issue with manufacturing an active pharmaceutical ingredient used in the drug. It is important to note that there are other alternatives that can be used by patients.

3. We are working with the manufacturer of this drug as well as other manufacturers to mitigate this shortage and will do everything possible to mitigate it. #COVID19

4. We have contacted over 180 human drug manufacturers to remind them of applicable legal requirements for notifying FDA of anticipated supply disruptions & to ask them to evaluate their entire supply chain, including active pharmaceuticals & other components manufactured in China.

2/29/20
Thread 2-- PPE:
1. We are currently not aware of specific widespread shortages of medical devices. [LINK TO SUPPLY CHAIN STATEMENT]
2. FDA has heard of increased demand & supply challenges of personal protective equipment (PPE)—gowns, gloves, surgical masks and/or respirator protective devices, or other equipment designed to protect the wearer from injury or the spread of infection or illness due to #COVID19
3. We are also aware of reports from @CDCgov & other partners of increased ordering of a range of human medical products as some healthcare facilities in the U.S. and preparing for potential future need if the outbreak were to become more serious.
4. We understand there are concerns about availability of PPE because of increased demand during the #COVID19 outbreak. This is not unexpected. If these supply challenges happen, we work closely with healthcare systems and local & regional health officials.

Week of 3/3/20
Thread 3—Blood/Biologics:
1. FDA is not aware of any cellular or gene therapies manufactured in China, and has identified no shortages of biologics as a result of supply chain disruptions from #COVID19 to report at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. The potential for transmission of #coronavirus by blood and blood components is unknown at this time; however, respiratory viruses, in general, are not known to be transmitted by blood transfusion.
3. There are no reported cases of transfusion-transmitted #COVID19.
4. The FDA has made information available to blood establishments and to establishments that manufacture human cells, tissues, or cellular or tissue-based products who may wish to consider additional donor screening measures in response to the #COVID19 outbreak.

3/2/20
Thread 4—Animal drugs:
1. There are 32 animal drug firms that make finished drugs in or source active pharmaceutical ingredients from China. @US_FDA has contacted all 32 firms & none have reported shortages as a result of #COVID19 at this time: [LINK TO SUPPLY CHAIN STATEMENT]
2. Although none of these 32 animal drug manufacturers have reported a shortage at this time, 6 firms have indicated that there have been disruptions in the supply chain that could soon lead to shortages. FDA is working with these firms to help identify interventions to mitigate any potential shortages.

Week of 3/3/20
Thread 5—Budget Proposal
1. The @US_FDA is using all our existing authorities to address #COVID19 and we welcome the opportunity to work with Congress to strengthen our #coronavirus response capabilities.
2. There are 4 specific proposals included in the President’s FY 2021 budget that would better equip the agency to prevent or mitigate medical product shortages. Learn more about FDA’s budget request: [LINK TO SUPPLY CHAIN STATEMENT]
From: Hinton, Denise /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/cn=RECIPIENTS/cn=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND
Sent: 2/28/2020 4:19:46 PM
To: Anderson, Erika /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eanders; Rebello, Heidi /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel; Caliguiri, Laura /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig; Lenihan, Keagan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Len
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

I agree with Erika’s comments and have no other suggestions. Thank you!

---

From: Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Sent: Friday, February 28, 2020 4:18 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

See edits below in blue.

For the first tweet, (b)(5)

---

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Friday, February 28, 2020 4:02 PM
To: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

See edits in red and in yellow below.

---

From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Friday, February 28, 2020 3:55 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: FOR FINAL CLEARANCE: OCC-CLEARED REVISED Supply chain statement tweets

For your approval OCC has cleared the following tweets on the supply chain statement.

Supply Chain Tweets

@SteveFDA Account
Individual tweets--- To be spread out

(b)(5)

3/1/20
2. See my update on how @US_FDA is monitoring the supply chain of FDA-regulated products and working to mitigate shortages during the #coronavirus outbreak: [LINK TO SUPPLY CHAIN STATEMENT]
2/29/20

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2/29/20

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Week of 3/3/20

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@US_FDA Account
Individual Tweets
2/29/20

Abigail Capobianco, MA
Writer/Editor
Social Media Lead
Incident Management Group (IMG) Joint Information Center (JIC)
2019 Novel Coronavirus (COVID-19) IMG
Center for Tobacco Products
Office of Health Communication and Education
U.S. Food and Drug Administration
Tel: 240-402-4715
abigail.capobianco@fda.hhs.gov
http://www.fda.gov/
CC: Sellers, Angela C (ACF) | /o=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=8e6728853b5a4b8ae1e3643837d93ae-ACF-Angela.
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; Bell, March (OS) | /o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: COVID-19 Response - alignment of OPDIV/STAFDIV Efforts
Attachments: COVID-19 Health Care System Resilience_Alignment of HHS Efforts_External_Agenda (2020-03-03) Final.docx; Key_Themes_Challenges_Gaps_(2020-03-03) FINAlxv2.docx; COVID-19 Health Care System Resilience_Alignment of HHS Efforts Meeting Deck_2020_03_03_VF.pptx
Location: Thomas P. O'Neill Federal Building - 200 C Street SW, ASPR Conference Center, Sub-Basement | Washington, DC 20515
Start: 3/4/2020 9:00:00 AM
End: 3/4/2020 10:15:00 AM
Show Time As: Busy

Required Attendees: Ford-Barnes, Arwenthia (OS/ASPR/O) Waters, Cicely (OS/ASPR/O) (Cicely.Waters@hhs.gov); Shuy, Bryan (OS/ASPR/O) (Bryan.Shuy@hhs.gov); Callahan, Victoria (OS/ASPR/O) (CTR); Moreno, Rafael (OS/ASA/O) (Rafael.Moreno@hhs.gov); Trueman, Laura (HHS/IEA); Rowell, Scott (OS/ASA); Bird, Catherine (OS/OGC);
Dear ASPR Colleagues,

We are at a critical juncture in our nation’s response to COVID-19. As we pivot from containment of the virus to mitigation of its impacts, it is imperative that HHS moves swiftly, transparently, and in a unified manner to protect lives and save Americans. The Secretary has charged my office to lead efforts across the Department to prepare and defend our health care system during the novel coronavirus outbreak through the Health Care System Resilience Task Force.

To date, this task force has engaged with public and private sector stakeholders to broadly identify efforts that can be taken to help ensure preparedness in response to a domestic COVID-19 outbreak, and more importantly their gaps, challenges, and potential areas of need from the federal government. Now, we must build on that knowledge to expedite and execute a whole of HHS response to support protection of the health care system that spans public health, health care, and human services.

Please join Dr. Kevin Yeskey, ASPR’s Principal Deputy Assistant Secretary for Preparedness and Response, and Dr. Nancy Messonnier, CDC’s Director of the National Center for Immunization and Respiratory Diseases, on **Wednesday, March 4 from 9:00 AM - 10:15 AM, at the O’Neill House Office Building** for a working session to align current activities and next steps to be executed as part of a coordinated HHS response to COVID-19.

Please provide the following information to (b)(6) no later than Monday, March 2 at 12:00 PM, and be prepared to share and discuss at Wednesday’s session.

- **Your Designee(s) name, title, and contact information**
- **OPDIV/STAFFDIV name**
- **OPDIV/STAFFDIV current and future top five priorities related to COVID-19 (priority leads, descriptions, timelines)**
- **OPDIV/STAFFDIV key activities and workgroups (current and under consideration) related to COVID-19 response (include activity/workgroup leads, key purpose, timelines)**
- **OPDIV/STAFFDIV key areas of concern or challenges identified to date**
- **OPDIV/STAFFDIV core competencies or other assets it can bring to COVID-19 response efforts**
We look forward to working with you on this critical effort to defend the nation’s health care system. Thank you in advance for your support and participation.

Respectfully,

Bob Kadlec  
ASPR

POC:  
Cicely L. Waters  
Director, Office of External Affairs  
Assistant Secretary for Preparedness and Response  
U.S. Department of Health and Human Services  
200 C St, SW  Washington, D.C. 20201  
(o) 202-205-0714  (m) (b)(6)  
cicely.waters@hhs.gov
Attached is the current WHO COVID-19 situation report.

-AN

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: ______ (b)(6) ______

FCCA | FDA Commissioned Corps Affairs
OTS | Office of Talent Solutions

U.S. FOOD & DRUG ADMINISTRATION

Hi all—

For your immediate review, here is the press release planning to issue tonight.

I spoke to Heidi and we also think we should send to Dr. Hahn now.

This is also in concurrent clearance. We will reconcile edits and flag any significant changes.

Thank you!
From: Malais, Tanya <Tanya.Malais@fda.hhs.gov>
Sent: Friday, February 28, 2020 6:49 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: COVID-19 Agency Executive Group meeting moving forward.

RDAM Hinton.

Attached are my notes from today's AEG meeting. Some of the AEG members speak rather quickly, so I hope I was able to captured everything the Commissioner needs.

Tanya E. Malais  
Documentation Unit Lead  
COVID-2019 IMG  
Office: 949-608-2984  
Mobile: (b)(6)  
Planning Section Email: 2019-nCoVFDAIMGPlanning@fda.hhs.gov  
24 hour Emergency Number: 1-866-300-4374

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you believe you have received this e-mail message in error, please e-mail the sender immediately at Tanya.Malais@fda.hhs.gov.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Friday, February 28, 2020 5:57 PM
To: Malais, Tanya <Tanya.Malais@fda.hhs.gov>
Subject: RE: COVID-19 Agency Executive Group meeting moving forward.

Thanks Tanya. Perfect timing as Dr. Hahn would like notes from today's meeting to review prior to his meeting at the WH tomorrow.

From: Malais, Tanya <Tanya.Malais@fda.hhs.gov>
Sent: Friday, February 28, 2020 2:37 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: COVID-19 Agency Executive Group meeting moving forward.

RADM Hinton,

Thank you for forwarding the Mon.-Thur. COVID-19 AEG meeting invitation to me so that I can capture any action items for the IMG. I do not have the meeting invitation for the Friday 4:30 pm AEG meetings. Can you please forward the Friday AEG meeting invitation to me?

Thank you,
Tanya E. Malais  
Documentation Unit Lead  
COVID-2019 IMG
From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Friday, February 28, 2020 2:13 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erik <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Susan.Mayne@fda.hhs.gov; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Finnen, April <April.Finen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Bess, Demetrie <Demetrie.Bess@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Torres-Rivera, Sahra <Sahra.Torres-Rivera@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: COVID-19 Agency Executive Group meeting moving forward.

Apologies – AEG call is 4:30 PM today...

From: Mair, Michael
Sent: Friday, February 28, 2020 2:09 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Tootle, William <William.Tootle@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Solomon, Steven M <Steven.Solomon@fda.hhs.gov>; Forfa, Tracey <Tracey.Forfa@fda.hhs.gov>; Rogers, Michael <Michael.Rogers@fda.hhs.gov>; McMeekin, Judith <Judith.McMeekin@fda.hhs.gov>; Abdoo, Mark <Mark.Abdoo@fda.hhs.gov>; Anderson, Erik <Erika.Anderson@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Susan.Mayne@fda.hhs.gov; Musser, Steven M <Steven.Musser@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Solberg, Tim <Tim.Solberg@fda.hhs.gov>
Cc: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Tyler, James <James.Tyler@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Malais, Tanya <Tanya.Malais@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Finnen, April <April.Finen@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>; Ricci, Linda J <Linda.Ricci@fda.hhs.gov>; O'Callaghan, Kathryn <Kathryn.OCallaghan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Bess, Demetrie <Demetrie.Bess@fda.hhs.gov>; Cho, David S (CBER) <David.Cho@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Ross, Bruce <Bruce.Ross@fda.hhs.gov>; Torres-Rivera, Sahra <Sahra.Torres-Rivera@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: COVID-19 Agency Executive Group meeting moving forward.
Hi. As discussed yesterday, for the daily AEG calls starting today and moving forward, the Commissioner would like to tick through the heck-list below. We will not be going over the SITREP, as everyone can read that. Instead this is intended to provide high-level updates on key issues and activities.

AEG representatives from Centers/Offices will be expected to report out on their respective areas. If you need additional people added to the call to support reporting out please advise.

Additionally as mentioned. After today’s AEG call this afternoon @ 4:15 PM, these check-in will be scheduled for 9:15 – 9:30 AM daily.

Thx - m

AEG DAILY CHECKLIST

(b)(5)
A few suggested edits for consideration if not too late.

Thanks,

Denise
This version reads well and captures suggested edits.

Thanks,

Denise

---

OCC cleared PR—can we flip to Dr. Hahn asap?

---

No. Pls clear before sending to Hahn.

Sent from my iPhone

On Feb 28, 2020, at 6:51 PM, Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov> wrote:

Hi all—
For your immediate review, here is the press release planning to issue tonight.
I spoke to Heidi and we also think we should send to Dr. Hahn now.

This is also in concurrent clearance. We will reconcile edits and flag any significant changes.

Thank you!

<Diagnostic guidance_PR draft 628pm_clearance.docx>
Today's FDA IMG COVID-19 Situation Report attached.

Respectfully,

Andrei Nabakowski, PharmD  
Captain, U.S. Public Health Service  
Director, FDA Commissioned Corps Affairs  
FDA Agency Liaison  
Andrei.Nabakowski@fda.hhs.gov  
Desk: 301-796-5205  
Cell: (b)(6)  

FCCA | FDA Commissioned Corps Affairs  
OTS | Office of Talent Solutions  
U.S. FOOD & DRUG ADMINISTRATION  

FDA-OSJI-FOIA-2020-3541_00001628
From: Capobianco, Abigail [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D8912265B9C85613BD-ABIGAIL.CAP]
Sent: 2/29/2020 3:11:34 PM
CC: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Thanks, Heidi!

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:10 PM
To: Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>

Subject: Fwd: FOR YOUR REVIEW: tweets for today's action (EUA policy)

I haven’t heard back from Commissioner yet on these but please let me know if you have any comments. I sent him text too.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:43:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>

Subject: FOR YOUR REVIEW: tweets for today's action (EUA policy)

Dr. Hahn, here are the ones related to today's action. Yours are first 4 threads for @Steve. Thank you.

EUA Press Release Tweets
@Steve FDA Account

Thread 1
1. Today, as part of our continuous approach to addressing #COVID19, FDA issued a policy regarding certain laboratories using tests they develop & validate for #coronavirus faster in order to achieve more rapid testing capacity in the U.S. Learn more: https://go.usa.gov/xddFR

2. Effective immediately, FDA does not intend to object to the use of these diagnostic tests to detect #COVID19 while such laboratories are pursuing an EUA with FDA.
3. We believe this policy strikes the right balance during this public health emergency. We will continue to help to ensure sound science prior to clinical testing and follow-up with the critical independent review from FDA, while quickly expanding testing capabilities in the U.S.

4. We are not changing our standards for issuing EUAs. Today’s action reflects our public health commitment to addressing critical public health needs and rapidly responding and adapting to this dynamic & evolving situation.

(b)(5)
(b)(5)
From: Capobianco, Abigail [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=660B8E4204F74D891226589C85613BD-ABIGAIL.CAP]
Sent: 2/29/2020 3:12:27 PM
To: Rebello, Heidi [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2ca0b-Heidi.Rebello]; Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85fe0694803be063e34a2ca0b-HINTOND]; Anderson, Erika [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64e6fbd25aba1e3573dfe-eranders]; Finnen, April [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d29184b0d9081e19bf-April.Fin
CC: Kimberly, Brad [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff925070f70b4c04-Kimberly.Brad]; Ru
Subject: RE: FOR YOUR REVIEW: NY State EUA tweets

Thank you!

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:12 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
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Subject: Fwd: FOR YOUR REVIEW: NY State EUA tweets

On NY announcement. Also haven’t heard back from Commissioner in these so please let me know if you have any comment.

__________________________________________________________________________________________

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:41:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FOR YOUR REVIEW: NY State EUA tweets

Dr. Hahn, please review tweets on NY State EUA to go once EUA is issued. Other tweets for today’s action coming your way separately.

NY STATE EUA TWEETS

2. Coordination across all levels of government & with public health partners domestically & abroad is one of the reasons we remain optimistic about our country’s preparedness & readiness despite the seriousness of the #COVID19 outbreak.
4. We recognize that increased testing capabilities are a crucial component to coordinated government efforts in response to the #coronavirus outbreak & continue to work with EUA developers to hasten the development & accessibility of critical medical products like diagnostics.
Thank you. I have a little time here. He made a statement during the presser, which I recorded and just published on US_FDA. I retweeted from his account.

I still have three other posts to make before EUA goes out. Hoping to do that one after dinner.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:10 PM
To: Finnen, April <April.Finnen@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: Fwd: FOR YOUR REVIEW: tweets for today's action (EUA policy)

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From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:43:00 AM EST
To: ‘Hahn, Stephen’ <SH1@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Subject: FOR YOUR REVIEW: tweets for today’s action (EUA policy)

Dr. Hahn, here are the ones related to today’s action. Yours are first 4 threads for @Steve. Thank you.

EUA Press Release Tweets
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3. We believe this policy strikes the right balance during this public health emergency. We will continue to help to ensure sound science prior to clinical testing and follow-up with the critical independent review from FDA, while quickly expanding testing capabilities in the U.S.

4. We are not changing our standards for issuing EUAs. Today’s action reflects our public health commitment to addressing critical public health needs and rapidly responding and adapting to this dynamic & evolving situation.
(b)(5)
Hi All,

CDRH just informed us that the target for approval is 7 p.m. tonight.

Thanks,
Abby

---

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:14 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: RE: FOR YOUR REVIEW: NY State EUA tweets

He's a WH so may respond shortly.

---

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, February 29, 2020 3:12 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>
Subject: Fwd: FOR YOUR REVIEW: NY State EUA tweets

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From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Date: February 29, 2020 at 11:41:00 AM EST
To: 'Hahn, Stephen' <SH1@fda.hhs.gov>
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NY STATE EUA TWEETS

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4. We recognize that increased testing capabilities are a crucial component to coordinated government efforts in response to the #coronavirus outbreak & continue to work with EUA developers to hasten the development & accessibility of critical medical products like diagnostics.
Signed. Many thanks to all of you!

Best,

Denise
From: Hinton, Denise /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBHF23SPDLT)/CN=RECIPIENTS/CN=85FECA08E0694803BE6030E97C7B4ADB-HINTOND
Sent: 3/2/2020 9:15:24 AM
To: Shah, Anand /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah
Subject: FW: COV-Supply Chain Coordination
Attachments: Supply Chain Options - N95 (PPE).pdf

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Date: March 2, 2020 at 9:11:41 AM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination

From: Jonas, Seth H. EOP/NSC
Sent: Saturday, February 29, 2020 9:41 PM
To: Eric.Rollison@cisa.dhs.gov; Glenn, Robert David.wade_@us.dhs.gov; Polowczyk, John P RADM USN JS J4 (USA 
M SES JS J4 (USA 
Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA 
LaBrecque, Michael F (Mike) COL USARMS DLA LOGISTICS OPERATIONS (USA 
Peck, Travis G MAJ USARMS DLA LOGISTICS OPERATIONS (USA 
Brown, Christopher K@dol.gov>; CoronavirusGlobalResponseCoordinationUnit _GlasserJL@dot.gov; donna.odberry@dot.gov; S60.Policy@dot.gov; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <saa1@cdc.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Smith, Matthew (OS) <Matthew.Smith@hhs.gov>; Falcon, Jessica (OS) <Jessica.Falcon@hhs.gov>; Cooper, Kevin (OS) <Kevin.Cooper@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Zebelye, Kyle (OS) <Kyle.Zebelye@hhs.gov>; Mastron, Hilary D (NIH) <Hilary.Mastron@nih.gov>; Heath.Trew@treasury.gov; Paul.Ahern@treasury.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal 
Edens, Mandy - OSHA <Mandy.edsen@osha.dol.gov>; Patel, Anita (CDC) <anita.patel@cdc.gov>; Hanson, Elizabeth A Col USAF JS J4 (USA 
Waterman, Paige E. EOP/OSTP <paige.waterman@ostp.gov>; Watson, Ian D. EOP/OSTP <ian.watson@ostp.gov>; Davis, May M. EOP/WHO <may.davis@who.int>; Honeycutt, Maria G. EOP/OSTP <maria.honeycutt@ostp.gov>; Sinclair, Michael R. EOP/NSC <michael.sinclair@ostp.gov>; Hoelscher, Douglas L. EOP/WHO <douglas.hoelscher@ostp.gov>; Goel, Andrea L. EOP/OMB <andrea.goel@omb.gov>; Chaffin, Kelly B. EOP/NSC <kelly.chaffin@ostp.gov>; Ferro, Phil J. EOP/NSC <phil.ferro@ostp.gov>; Fabina, Lauren C. EOP/NSC <lauren.fabina@ostp.gov>; Nicholas W. EOP/WHO <nicholas.w.nicholas@who.int>; Abbott, Christopher J. EOP/WHO <christopher.abbott@who.int>; Troye, Olivia EOP/NSC <olivia.troye@ostp.gov>; Farquharson, Christine E. EOP/OMB <christine.farquharson@ostp.gov>; amie.kalsbeek@dot.gov; Bedan, Morgan E. EOP/WHO <morgan.beden@ostp.gov>; Cavanaugh, Brian J. EOP/NSC <brian.cavanaugh@ostp.gov>; david.short@dot.gov; Krohmer, Jon (NHTSA) <john.krohmer@dot.gov>; Holmes, Benjamin Carlson <benjamin.carlson@trade.gov>; Kroese, Daniel <Daniel.Kroese@hhs.gov>; Stevens, Kathleen E <kathleen.stevens@hhs.gov>; Tewell, Adam (OS) <Adam.Tewell@hhs.gov>; Elvander, Erika (OS) <Erika.Elvander@hhs.gov>;
Subject: COV-Supply Chain Coordination

Dear Supply Chain Coordination Working Group (SSCWG),

Attached please find the document sent out on potential courses of action (COAs) for supply chain issues associated with N95 respirators.

Thank you for your contributions towards developing this document, and I look forward to your continued engagement.

Seth.

Seth Jonas, PhD
Director for Critical Infrastructure
Director for Preparedness
National Security Council
Hi- just making sure this is being addressed so the information can be provided before 1:30 today. Patrizia provided talking points regarding chloroquine. Need the others ASAP. Please respond and let me know you have received this and are acting on it.

Thank you!

Update: Dr. Hahn is joining a 12 PM Media Telebriefing, hosted by CDC. It will be Dr. Hahn and Dr. Messonnier to provide an update on COVID-19 response.

Good morning Denise,

Starting a thread on items Dr. Hahn is requesting for today (taskforce meeting is at 3 PM, would be best to have any items by 1:30 PM for printing at his departure from WO, otherwise prior to 3 PM he can have them digitally for Task Force Mtg):

(b)(5)
Please let me know if I can get any request calcification details from Dr. Hahn, or if we can be of any assistance in reaching out to collect these items prior to Dr. Hahn's taskforce meeting today.

Thank you,
Frank

Frank A. Olivarria
Management and Program Analyst
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Tel: 240-402-9882
Frank.Olivarria@fda.hhs.gov
We can discuss the highlighted information in yellow tomorrow morning and provide him with decision/input later?

Supply Chain Updates:

• **Requests for more detailed supply chain information:** We’ve been receiving requests from USG (HHS, DHS, DoD) and international (WHO, individual NRAs) partners for **more detailed supply chain information, especially on the**

(b)(5)

• **SNS:** Deploying some PPE (including some “expired” surgical masks) to Washington State to address supply challenges.
FYI only – letter from Rep. Jackson Lee to POTUS re: CoV response. Click the paperclip in left toolbar to view the letter.

Yeah, I know, the Congresswoman’s staff needs to proofread communications before sending them out.

---

Good afternoon,

The attached document is being sent to you as an FYI.

Val

“TIMELESS TURTLE – STEADY, DEPENDABLE, STRONG”
Jennifer,

Attached is the signed document. Many thanks to all of you for your work on this.

Best,

Denise

---

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, March 2, 2020 4:35 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For signature today: CDC EUA for certain respirators

RADM Hinton,

For your signature (today) is the attached letter to issue an EUA to CDC for emergency use of certain respirators.

The EUA Declaration that was needed, has been signed by the Secretary already today.

The letter was cleared by CDRH (S.Schwartz), OCC (C.Dennis), and OCET (M.Mair) today.

For reference, CDC’s request letter is attached and Appendix A referenced in the letter of authorization. Appendix B referenced in the letter of authorization is currently blank (and not attached), as authorized respirators will be added to it over time.

If you have any questions, then please let me know.

Thanks!

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-5155
Jennifer.Ross@fda.hhs.gov
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Were they coordinating distribution of tests? Fortunately, it does note that things will get better. Could we 1.

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By Jon Cohen Feb. 28, 2020, 5:45 PM

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In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID-19 case without known links to an infected person.

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The situation may soon improve. State labs and commercial diagnostic developers hope to win approval from the Food and Drug Administration (FDA) for their own tests, and FDA and CDC on Wednesday agreed on a workaround for the faulty CDC kit—which has a problem that is not essential to its proper functioning—so that it can now be used by at least some of the state labs that have it.

But there’s widespread discontent with the way the system has worked. “The U.S. government has not appropriately prioritized diagnostic tests and supported the laboratory response network to the degree they should have been supported over the years,” says Luciana Borio, who in previous jobs had lead roles in responding to emerging threats at the National Security Council and FDA.

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From: Mair, Michael [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHFB23SPDLT)/CN=RECIPIENTS/CN=4F511BDAD7564D7FA7EAD7C7961467AB-MICHAEL.MAIR]

Sent: 3/2/2020 6:15:38 PM


RE: Science Magazine Article

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FDA-OSJI-FOIA-2020-3541_00000985
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From: Caliguiri, Laura 
To: Mair, Michael 
Sent: 3/2/2020 6:20:13 PM 
Cc: 
Subject: RE: Science Magazine Article

+ Peter who is in communication with WHO on this. Will let Peter share her response in detail but topline, this is inaccurate. They don’t ship testing kits, they do provide assays.


From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, March 2, 2020 5:55 PM 
To: Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov> 
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
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From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 2, 2020 at 5:18:15 PM EST
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>, Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>, Ross, Aftin <Aftin.Ross@fda.hhs.gov>, Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>, Busch, Marcy <Marcy.Busch@fda.hhs.gov>, Beers, Donald <Donald.Beers@fda.hhs.gov>, Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>, Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>, Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>, Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>, Russ, Wanda <Wanda.Russ@fda.hhs.gov>, McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>, Finnen, April <April.Finnen@fda.hhs.gov>, Marders, Julia A <Julia.Marders@fda.hhs.gov>, Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

RADM Hinton,

Thank you for your help and support with this important effort!

Suzanne

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996
Thank you!

Denise

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, March 2, 2020 4:59 PM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrener, Elizabeth J <Elizabeth.Hillebrener@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Adding Denise for awareness...

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Monday, March 02, 2020 4:57 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrener, Elizabeth J <Elizabeth.Hillebrener@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: RE: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Hey folks—we are just waiting on VP’s office to clear press release. Hopefully we can post soon.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, March 02, 2020 4:51 PM
To: Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>; Chang, Cynthia <Cynthia.Chang@fda.hhs.gov>
Cc: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hillebrener, Elizabeth J <Elizabeth.Hillebrener@fda.hhs.gov>; Russ, Wanda <Wanda.Russ@fda.hhs.gov>; McSeveney, Megan <Megan.McSeveney@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Marders, Julia A <Julia.Marders@fda.hhs.gov>; Agler, Heather L <Heather.Agler@fda.hhs.gov>
Subject: FYI - Signed EUA Letter of Authorization to CDC for Respirators

Hello,
Please find attached the signed EUA Letter of Authorization (PDF), and Word Version.

An “umbrella” EUA was issued to CDC today for emergency use of certain respirators.

The issuance of the EUA is pursuant to HHS’s February 4\textsuperscript{th} determination that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19 and the subsequent declaration from HHS earlier today that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak.

Congratulations to the team!

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov
Hi Keagan and Denise,

As mentioned earlier, attached for your review is the draft background document for LOE2 of the NSC Supply Chain Coordination WG. Do you have any edits or concerns? It’s intended to very high level, in part to describe the complexities of the problem but also because other LOEs will be covering specific products (e.g., PPE, needles/syringes, investigational products).

Thanks,
Brooke
From: Hinton, Denise
Sent: 3/2/2020 8:00:48 PM
To: Lenihan, Keagan
CC: Courtney, Brooke; Mair, Michael
Subject: FW: NSC LOE2: Supply Chain Summary (due tonight)
Attachments: LOE2 NSC SC Background WG 3.2.20 DRAFT.pm.docx
Importance: High

Reviewed – no edits or concerns from me.

Thank you!
Denise

From: Courtney, Brooke
Sent: Monday, March 2, 2020 7:15 PM
To: Lenihan, Keagan; Hinton, Denise
Cc: Mair, Michael
Subject: NSC LOE2: Supply Chain Summary (due tonight)
Importance: High

Hi Keagan and Denise,

As mentioned earlier, attached for your review is the draft background document for LOE2 of the NSC Supply Chain Coordination WG. Do you have any edits or concerns?

(b)(5)

Thanks,
Brooke
We agree with your approach – thank you for crafting the remarks/TPs for review and clearance.

Best,
Denise
From: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>
Sent: Monday, March 2, 2020 7:25 PM
To: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Yes, there are several publications that I'll be reaching out to, thanks for following up.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 02, 2020 7:13 PM
To: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: RE: Science Magazine Article

Extremely helpful. I neglected to include Stephanie on this chain. Stephanie and Laura (b)(5)
From: Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
Date: March 2, 2020 at 7:06:18 PM EST  
To: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>, Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Janik, Heather <Heather.Janik@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Gross, Karas <Karas.Gross@fda.hhs.gov>, Black, Jennifer <Jennifer.Black@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>, Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>  
Subject: RE: Science Magazine Article

Thanks again all.

Jeff said WHO confirmed that they have not made a test, shipped a test, or listed a test. The news stories are not accurate, so we should be clear about it.

Best,

Jennifer Brown Tomasello, MPA  
Senior Policy Advisor  
Center for Devices and Radiological Health  
Office of Policy  
U.S. Food and Drug Administration  
Tel: 301-796-8924  
jenjtom@fda.hhs.gov

---

From: Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>  
Sent: Monday, March 2, 2020 6:20 PM  
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Janik, Heather <Heather.Janik@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Cc: Lutter, Randall <Randall.Lutter@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>  
Subject: Re: Science Magazine Article

Looping in Tim and Jennifer.

---

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
The United States badly bungled coronavirus testing—but things may soon improve

By Jon CohenFeb. 26, 2020, 5:45 PM

Speed is critical in the response to COVID-19. So why has the United States been so slow in its attempt to develop reliable diagnostic tests and use them widely?

The World Health Organization (WHO) has shipped testing kits to 57 countries. China had five commercial tests on the market 1 month ago and can now do up to 1.6 million tests a week; South Korea has tested 65,000 people so far. The U. S. Centers for Disease Control and Prevention (CDC), in contrast, has done only 459 tests since the epidemic began. The rollout of a CDC-designed test kit to state and local labs has become a fiasco because it contained a faulty reagent. Labs around the country eager to test more suspected cases—and test them faster—have been unable to do so. No commercial or state labs have the approval to use their own tests.
In what is already an infamous snafu, CDC initially refused a request to test a patient in Northern California who turned out to be the first probable COVID19 case without known links to an infected person.

The problems have led many to doubt that the official tally of 60 confirmed cases in the United States is accurate. The official tally of 60 confirmed cases in the United States is accurate. “There have been blunders, and there could be an underlying catastrophe that we don’t know about,” says epidemiologist Michael Mina, who helps run a microbiology testing lab at Brigham and Women’s Hospital. “It’s been very complicated and confusing for everyone with almost no clarity being provided by the CDC.”

The situation may soon improve. State labs and commercial diagnostic developers hope to win approval from the Food and Drug Administration (FDA) for their own tests, and FDA and CDC on Wednesday agreed on a workaround for the faulty CDC kit—which has a problem that is not essential to its proper functioning—so that it can now be used by at least some of the state labs that have it.

But there’s widespread discontent with the way the system has worked. “The U.S. government has not appropriately prioritized diagnostic tests and supported the laboratory response network to the degree they should have been supported over the years,” says Luciana Borio, who in previous jobs had lead roles in responding to emerging threats at the National Security Council and FDA.

If a new disease emerges, CDC normally “gets the ball rolling” with diagnostics because it has the expertise and the biosafety laboratories to handle dangerous novel pathogens, says Borio, who now works for In-Q-Tel, a not-for-profit venture capital firm. Typically, there are few confirmed viral samples from patients at the outset, which researchers need to validate their tests, and CDC has the capability to grow the virus for this critical quality assurance step. Once the agency has a working test, that goes out to state labs. Then, in a third phase, commercial labs take over and either produce their own tests or scale-up the CDC one. “I would have hoped to see that third phase by now,” Borio says.

In the case of SARS-CoV-2, as the virus causing COVID-19 is officially known, CDC’s sluggishness was apparent 1 month ago. On 26 January, the agency held an unusual Sunday teleconference for the media to provide an update about the rapidly growing outbreak. There were then five cases in the United States, but the CDC lab in Atlanta was still the only one in the country able to test for the virus, and it repeatedly had backlogs. Asked why more labs weren’t able to do the tests, Nancy Messonnier, who then was leading CDC’s response, said it was a quality issue. “We hold ourselves to an incredibly high standard of precision in terms of laboratory testing,” Messonnier said. “We wouldn’t want to inadvertently make a mistake in patient care.”

CDC finally started to send kits to state and local health labs on 5 February. But on 12 February, it revealed that several labs had difficulty validating the test because of a problem with one of the reagents.

The key problem with the kits is what’s known as a negative control, says Kelly Wroblewski, director of infectious diseases at the Association of Public Health Laboratories (APHL). CDC’s test uses the polymerase chain reaction (PCR) assay to find tiny amounts of the SARS-CoV-2 genome in, say, a nose swab. To make sure a test is working properly, kits also include DNA unrelated to SARS-CoV-2. The assay should not react to this negative control, but the CDC reagents did at many, but not all, state labs. The labs where the negative control failed were not allowed to use the test; they have to continue to send their samples to Atlanta.

The declaration of a public health emergency ... limited the diagnostic capacity of this country. It’s insane.

Michael Mina, Brigham and Women’s Hospital

In principle, many hospital and academic labs around the country have the capability to carry out tests themselves. The PCR reaction uses so-called primers, short stretches of DNA, to find viral sequences. The CDC website posts the primers used in its test, and WHO publicly catalogs other primers and protocols, too.
Well-equipped state or local labs can use these—or come up with their own—to produce what are known as a “laboratory-developed tests” for in-house use.

But at the moment, they’re not allowed to do that without FDA approval. When the United States declared the outbreak a public health emergency on 31 January, a bureaucratic process kicked in that requires FDA’s “emergency use approval” for any tests. “The declaration of a public health emergency did exactly what it shouldn’t have. It limited the diagnostic capacity of this country,” Mina says. “It’s insane.”

On 24 February, APHL asked FDA Commissioner Stephen Hahn for “enforcement discretion” to sidestep the emergency process and allow APHL members labs to use their own tests. On 26 February, Hahn replied that the CDC test could be modified to use just the primers that specifically detect SARS-CoV-2, essentially ignoring the faulty portion of the kits. FDA, in other words, would look the other way to make more widespread testing possible.

CDC has notified labs of FDA’s decision in a letter, but the agency must still file an emergency use authorization with FDA for the protocol change. Once it does, it won’t take long, Hahn promised in his letter to APHL: “FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation.”

In New York, the State Department of Health has designed its own test based on the CDC protocol and plans to seek emergency use authorization.

CDC provided an update about the situation in an email but did not respond to Science’s request for an interview with a scientist to discuss the details of the problem. Mina stresses he has great respect for CDC’s competence overall, but says, “There’s no good explanation for what’s going on here.”
During a briefing on the novel Coronavirus at his office in midtown Manhattan, Governor Andrew M. Cuomo today announced the world-renowned Wadsworth Center — the research-intensive public health laboratory housed within the State Department of Health — is partnering with hospitals to expand surge testing capacity to 1,000 tests per day statewide for the novel coronavirus. The Wadsworth Center will provide these hospitals with instructions on how to replicate the State’s test, as well as help them purchase some of the equipment necessary to develop and validate the test.
Both – please and thank you.

Marcy or Liz? – in the letter “Testing is limited to the Wadsworth Center, New York State Department of Public Health ("Wadsworth Center NYSDOH"), and the New York City Department of Health and Mental Hygiene, Public Health Laboratories ("NYC DOHMH/PHL")”

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov
From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:07 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Liz for engagement – thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:05 AM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Let me know pls.

Sent from my iPhone

On Mar 3, 2020, at 9:45 AM, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov> wrote:

Are they allowed to do that – (b)(5)

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

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White Oak, Bldg. 66, Rm. 3216 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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<image009.jpg>
<image010.jpg>
<image011.jpg>
<image012.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcuservice?ID=1932&S=E.
During a briefing on the novel Coronavirus at his office in midtown Manhattan, Governor Andrew M. Cuomo today announced the world-renowned Wadsworth Center — the research-intensive public health laboratory housed within the State Department of Health — is partnering with hospitals to expand surge testing capacity to 1,000 tests per day statewide for the novel coronavirus. The Wadsworth Center will provide these hospitals with instructions on how to replicate the State's test, as well as help them purchase some of the equipment necessary to develop and validate the test.
From: Shah, Anand [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855FS1-ANAND.SHAH]
Sent: 3/3/2020 10:36:56 AM
To: McWilliams, Carly [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/cn=b68c7458214244d08424fd441fe4FDA-Carlyle.McW]; Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/cn=85feca0be0694803b6030e97c7b4adb-HINTOND]
Subject: FW: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York
Attachments: NYS DOH EUA Letter of Authorization 02292020 FINAL.pdf

+Carly

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

BLUF: Under the EUA, the authorized labs were just the two labs (Wadsworth and NYC DOHMH/PHL) and there was no provision to add more authorized laboratories.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:28 AM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Under the EUA, the authorized labs were just the two labs (Wadsworth and NYC DOHMH/PHL) and there was no provision to add more authorized laboratories.

Thanks,

Jennifer

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:15 AM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
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Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Jennifer...

From: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:08 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Marcy or Liz? – in the letter “Testing is limited to the Wadsworth Center, New York State Department of Public Health (“Wadsworth Center NYSDOH”), and the New York City Department of Health and Mental Hygiene, Public Health Laboratories (“NYC DOHMH/PHL”)”

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)

CDRH | Food and Drug Administration
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Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

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From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 10:07 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>

Subject: RE: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Adding Liz for engagement – thanks.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 10:05 AM
To: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Roth, Kristian <Kristian.Roth@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: At Novel Coronavirus Briefing, Governor Cuomo Announces State is Partnering with Hospitals to Expand Novel Coronavirus Testing Capacity in New York

Let me know pls.

Sent from my iPhone

On Mar 3, 2020, at 9:45 AM, Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov> wrote:

Are they allowed to do that – [(b)(5)]

Kim Sapsford-Medintz, Ph.D.
MCM EUA Team Lead
Bacterial Respiratory and Medical Countermeasures Branch
Division of Microbiology Devices | OHT7: Office of In-vitro Diagnostic and Radiological Health (OIR)
Office of Product Evaluation and Quality (OPEQ)
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3216 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-0311
Kim.Sapsford@fda.hhs.gov

<image007.png>

<image008.jpg>
<image009.jpg>
<image010.jpg>
<image011.jpg>
<image012.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
https://www.research.net/s/cdrhcustomerservice?ID=1932&S=E.
During a briefing on the novel Coronavirus at his office in midtown Manhattan, Governor Andrew M. Cuomo today announced the world-renowned Wadsworth Center — the research-intensive public health laboratory housed within the State Department of Health — is partnering with hospitals to expand surge testing capacity to 1,000 tests per day statewide for the novel coronavirus. The Wadsworth Center will provide these hospitals with instructions on how to replicate the State's test, as well as help them purchase some of the equipment necessary to develop and validate the test.
Per our discussion yesterday.

Thank you,

Denise
The attached talking points are cleared by JIC/IMG and OCC. Thank you.

-April

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:52 AM
To: Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARENCE: TP for Press Conference

Good morning-thanks for your help, then please clear this version. This needs to be cleared for Hahn at 1.

From: Finnen, April <April.Finnen@fda.hhs.gov>
Date: March 3, 2020 at 7:18:47 AM EST
To: Mair, Michael <Michael.Mair@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: TP for Press Conference

Happy to help. What time is the press conference today (i.e., when does this need to be cleared by)? And is the version Michael sent the one you want IMG-cleared?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, March 2, 2020 10:46 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: RE: FOR CLEARANCE: TP for Press Conference

Hi – some suggestions attached – use whatever works.

Copying April who can help push through JIC clearance once u have final version u want cleared. Thx - m

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 2, 2020 9:44 PM
Thanks Stephanie and Carly. Just a minor suggested edit from me. Michael will review shortly.

Best,

Denise

Hi, attached are talking points for tomorrow’s press conference that Stephanie and I drafted. Wanted to let you both review first and then would appreciate your help with clearance. Is there someone that does clearance at the IMG?

(b)(5)
I am on a call now but I wanted to flag these materials for you both. I will let you know when I hear back from Jeff (should be by 1:30). Once I finalize these I think we should save them in SharePoint so we can use as base for tomorrow’s materials.

TP for Press Conference (from April, cleared JIC/IMG)

[Attachment: 20200303HahnTPsforWHTFOCCleared_clean.docx]

Background document for Dr. Hahn’s briefing this afternoon
 stilpending clearance from Shuren/CDRH) Highlighted new information.

[Attachment: WHTF Briefing 03.03.2020 COM..]
From: Caliguiri, Laura [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPENTS/CN=AA086F26C0346C49E996932D86AC62E-LAURA.CALIG]
Sent: 3/3/2020 2:10:11 PM
CC: 
Subject: RE: NYTimes

RE: NYTimes

(b)(5)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 2:07 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: NYTimes

(b)(5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 03, 2020 2:00 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Stephanie and I are Flagging an additional NYTimes story and looping in oma. Reporters are confused based on the language about performance of tests. I understand that he is trying to express availability of tests but not necessarily that all the tests will be ready to be run.

Stephanie did I miss anything?

**Trump Administration Sends Mixed Signals on Coronavirus Testing**

The Food and Drug Administration chief said Tuesday that enough tests would be on hand this week for a million virus tests, but the actual number of tests administered will likely be far lower.
“I don’t think that we are going to get out of this completely unscathed.” Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, said. Credit...Anna Moneymaker/The New York Times

By Noah Weiland and Emily Cochrane

WASHINGTON — The Trump administration sent mixed signals on Tuesday about how quickly testing for the coronavirus would ramp up, stressing that close to a million coronavirus tests should be available this week but also that the number of tests to be administered remained unknown.

Dr. Stephen Hahn, the commissioner of the Food and Drug Administration, said at a Senate hearing that the Centers for Disease Control and Prevention was working with a private manufacturer to drastically increase the testing capacity of laboratories across the nation.

“Our expectation in talking to the company that is scaling this up is that we should have the capacity by the end of the week to have kits available to the laboratories to perform about a million tests,” he said.

White House officials, however, stressed that the number of tests actually administered could be considerably lower. When Dr. Hahn was asked to clarify, he said that he was hearing from private manufacturers that 2,500 test kits could be available by the end of the week, with each kit capable of 500 tests.

“This is a dynamic process,” Dr. Hahn said. “Every day we’re hearing from additional manufacturers.”

The F.D.A. has said that Dr. Hahn was taking into account the anticipated production of test kits by Integrated DNA Technologies, which is now selling kits to the federal government and other buyers. But that would not increase the capacity of individual labs to perform the tests.
The confusion typified the struggle by the Trump administration to project confidence and progress without misleading the public about the virus’s spread. New infections in Westchester County, N.Y., San Mateo County, Calif., and Fulton County, Ga., since Monday evening made clear coronavirus was spreading in the sprawl of America’s largest urban centers and was no longer tethered to international travelers. In the United States, there have been at least 105 cases of coronavirus confirmed by lab tests as of Tuesday morning, and worldwide infections topped 92,200.

Dr. Anthony S. Fauci, director of the National Institute of Allergy and Infectious Diseases, told Politico that Americans should expect the outbreak to worsen.

“I don’t think that we are going to get out of this completely unscathed,” he said. “I think that this is going to be one of those things we look back on and say, ‘boy, that was bad.’”

Get an informed guide to the global outbreak with our daily coronavirus newsletter.

The number of tests that will be administered in the coming days could be substantially lower than the projection Dr. Hahn had offered. A spokesman for the Department of Health and Human Services said Monday that public health labs currently can test 15,000 people, and could test up to 75,000 by the end of the week, numbers that fall well short of what Dr. Hahn suggested could result from private manufacturing.

The Association of Public Health Laboratories, which represents state and local government laboratories around the country, has said that its labs would be able to conduct about 10,000 tests a day when all of its 100 members that can perform testing are running. Scott Becker, the executive director of the lab association, said Monday that labs can run about 100 tests per day. As of Monday, he said fewer than half of those labs were able to do so.

Dr. Fauci told Politico that he would be truthful in his public pronouncements, even as President Trump sought to minimize the virus’s impact.

“You should never destroy your own credibility. And you don’t want to go to war with a president,” Dr. Fauci told Politico in an interview Friday. “But you got to walk the fine balance of making sure you continue to tell the truth.”

At several hearings across Capitol Hill on Tuesday morning, other Trump administration officials spoke to different elements of the federal response.

Chad Wolf, the acting secretary of the Department of Homeland Security, told the House Homeland Security Committee on Tuesday that he ordered a department field office in King County, Wash., to close for 14 days after learning that one of its employees visited a relative at Life Care Center in Kirkland, Wash., a nursing home where four of the six Americans who have died of the virus lived.

Mr. Wolf said he also directed employees at the field office to quarantine themselves for 14 days.

The employee visited Life Care Center before it became a focal point of the outbreak, Mr. Wolf said.

“This employee embodied leading by example,” Mr. Wolf said.

In another hearing, Steven Mnuchin, the Treasury secretary, said that the Trump administration is working with other countries to do everything possible to curb the spread of the virus and to limit damage to the global economy.

“The administration is closely monitoring the coronavirus and its effect on public health as well as any effects on supply chains, markets and the broader economy,” Mr. Mnuchin said, adding that the White House wanted to work closely with Congress for emergency funding.

Representative Richard Neal of Massachusetts, the chairman of the House Ways and Means Committee, told Mr. Mnuchin that any stimulus package should be centered around infrastructure investment rather than additional tax cuts.

“If there’s a need to stimulate the economy as a result of the coronavirus, I’m sure that infrastructure is a priority of the president,” Mr. Mnuchin said.

Mr. Mnuchin said the Trump administration was not considering rolling back or suspending its tariffs on Chinese imports to mitigate the economic effects of the coronavirus.

He said that the Treasury Department had set up a group to begin looking at tax measures that the Trump administration could take to provide relief to small and medium-sized businesses. He said that the White House could present proposals to Congress for such action if needed.
As the Trump administration officials testified, lawmakers were working on an emergency spending bill, hoping to pass it before a mid-March break. The legislation, which could be unveiled Tuesday, is expected to be worth $7 billion to $8 billion.

The package, which has been quickly negotiated over the past few days, is expected to be significantly larger than what the White House initially proposed eight days ago: $1.25 billion in new funds, paired with a transfer of existing funds from other health programs.

Zolan Kanno-Youngs and Alan Rappeport contributed reporting from Washington, Katie Thomas from Chicago and Knvul Sheikh from New York.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 12:31 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: NYTimes

https://www.nytimes.com/2020/03/03/health/coronavirus-tests-fda.html

Carly – Can we pass this to OEA / CDRH

Anand
Keagan’s point is where I was headed with my earlier comment – need to make it understandable to the public, and I think Keagan said it well.
Stephanie and I are Flagging an additional NYTimes story and looping in OMA. Reporters are confused based on the language about performance of tests. I understand that he is trying to express availability of tests but not necessarily that all the tests will be ready to be run.

(b)(5) Stephanie did I miss anything?

Trump Administration Sends Mixed Signals on Coronavirus Testing

The Food and Drug Administration chief said Tuesday that enough tests would be on hand this week for a million virus tests, but the actual number of tests administered will likely be far lower.

By Noah Weiland and Emily Cochrane

- March 3, 2020, 12:43 p.m. ET
WASHINGTON — The Trump administration sent mixed signals on Tuesday about how quickly testing for the coronavirus would ramp up, stressing that close to a million coronavirus tests should be available this week but also that the number of tests to be administered remained unknown.

Dr. Stephen Hahn, the commissioner of the Food and Drug Administration, said at a Senate hearing that the Centers for Disease Control and Prevention was working with a private manufacturer to drastically increase the testing capacity of laboratories across the nation.

“Our expectation in talking to the company that is scaling this up is that we should have the capacity by the end of the week to have kits available to the laboratories to perform about a million tests,” he said.

White House officials, however, stressed that the number of tests actually administered could be considerably lower. When Dr. Hahn was asked to clarify, he said that he was hearing from private manufacturers that 2,500 test kits could be available by the end of the week, with each kit capable of 500 tests.

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The confusion typified the struggle by the Trump administration to project confidence and progress without misleading the public about the virus’s spread. New infections in Westchester County, N.Y., San Mateo County, Calif., and Fulton County, Ga., since Monday evening made clear coronavirus was spreading in the sprawl of America’s largest urban centers and was no longer tethered to international travelers. In the United States, there have been at least 105 cases of coronavirus confirmed by lab tests as of Tuesday morning, and worldwide infections topped 92,200.

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Zolan Kanno-Youngs and Alan Rappeport contributed reporting from Washington, Katie Thomas from Chicago and Knvul Sheikh from New York.

---

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 12:31 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Cc: Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: NYTimes

https://www.nytimes.com/2020/03/03/health/coronavirus-tests-fda.html

Carly – Can we pass this to OEA / CDRH (b)(5)

Anand
Looping in others for situational awareness.

From Jeff:

(b)(4) (b)(5)

Just need you to get an answer (b)(5). Don’t worry about the rest, thanks.
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 6:17 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Update w/ test #s from this morning

I pinged Jeff but does Giroir’s email mean (b)(5)? I wasn’t sure what be with them means.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 3, 2020 at 5:38:17 PM EST
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: Update w/ test #s from this morning

I need to know why we (b)(5)
Hi Carly. I have asked that you be given access to SharePoint. I’ve loaded these docs in a folder for White House Briefings, which you are welcome to use going forward. Any time you need talking points routed for JIC/IMG and OCC review, please let me know and the JIC can assist. I’m working on identifying additional team members who can help monitor for and cover these late evening requests if things need to be routed immediately. The JIC members work closely with their IMG operations counterparts (e.g., CDRH for devices), so we can help you get these things in front of the right people to review quickly. We just need to know when you need the OCC-cleared version back. Happy to discuss our process, and work with you to streamline—just let me know.

Thanks,
April

p.s. We have an OCC-cleared talking points list that is updated almost daily now with the latest. You can find it in the SP Talking Points folder.

Hello! Only read out on press gaggle and meeting this evening is a request for talking points for VP meeting with diagnostic manufacturers (which they set up today). I drafted and sent to CDRH for clearance.

Did we send decision memo to Keagan and commissioner re: travel? Also updated status of projects below: please let me know what I am missing. Thank you.

I created a working list of all items we are working on. Could you both review and add items I may be missing.my goal is to send this out tonight with action items from the WHTF meeting.
Thank you for Kristian - this was meant for Lauren Roth and I sent it to her following your email.

Have a great day!

Denise
We have received from questions from OMB (see attached) on our “plan” for issuing the CDRH enforcement discretion guidance. But, some of them (most of them) are really questions for CMS or others in the Department. Is there someone at HHS that could help identify the right POCs to respond? Happy to discuss if that’s easier. Unfortunately, I think we’re trying to get back to OIRA by tomorrow, so I need to find the right person asap. Keagan suggested I ask if you could direct me.

Thanks,
Lauren

From: Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:22 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

My thoughts, see attached.

Best,
Tim

Timothy T. Stenzel, MD, PhD
Director, OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
U.S. Food and Drug Administration
Timothy.Stenzel@fda.hhs.gov
Jennifer Campbell
Administrative Assistant
OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66 3403 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: 301-796-7692
Jennifer.Campbell@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/r/co/codenicecustomerservice?ID=1800&S=E

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 7:11 PM
To: Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Foy, Jonette <Jonette.Foy@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Schwartz, Suzanne <Suzanne.Schwartz@fda.hhs.gov>; Ross, Aftin <Aftin.Ross@fda.hhs.gov>
Cc: Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

All,
We received the following email from OIRA, with questions on our original “plan” document. My best guess is that these questions are stragglers (given that they are reflected on the plan and not the guidance itself), but HHS has asked us to respond by tomorrow.

Let me know if you would like to discuss.

Thanks,
Lauren

From: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Sent: Tuesday, March 3, 2020 1:06 PM
To: Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; OC OPPB OP RPMS <OCOPPBOPRPMS@fda.hhs.gov>
Subject: FW: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Lauren,

Please find attached some follow-up questions from the Medicare team of OIRA. If FDA could provide bubble responses on the attached by tomorrow, that would be great.

Thank you

From: Hirsch, Quinn N. EOP/OMB <b>(b)(5)</b>
Sent: Tuesday, March 3, 2020 12:57 PM
To: Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>
Cc: Fischbach, Aaron (OS/IOS) <Aaron.Fischbach@hhs.gov>
Subject: CMS/FDA: Questions regarding FDA plan for COVID-19 Testing

Hi Kat,

(b)(5)

Thanks,
Q

Quinn N. Hirsch, MPH
Office of Information and Regulatory Affairs

(b)(6)

(she/her/hers)
Sent: Wednesday, March 4, 2020 8:46 AM
To: Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Thorpe, Valarie <Valarie.Thorpe@fda.hhs.gov>; Meyer, Lyndsay <Lyndsay.Meyer@fda.hhs.gov>; Stark, Angela <Angela.Stark@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: TWEETS for REVIEW: HELP Testimony // Feed Your Mind

Look good. Keagan, 

S

Sent from my iPad

On Mar 4, 2020, at 8:25 AM, Kimberly, Brad <Brad.Kimberly@fda.hhs.gov> wrote:

Good morning... two threads for your review this AM. Thanks! --Brad

===

HELP Testimony

1. Yesterday, I had the opportunity to update the senate HELP committee about FDA’s latest actions addressing #COVID19 outbreak, including the availability of diagnostics as industry ramps up production. [VIDEO CLIP]

2. In addition to CDC continuing distribution of their test, we have heard from a commercial manufacturer that they will be ramping up production of CDC’s authorized test & produce more than 1 million tests by the end of this week. https://www.fda.gov/news-events/congressional-testimony/hearing-emerging-disease-threat-how-us-responding-covid-19-novel-coronavirus-03032020

3. Going forward, this manufacturer expects to produce significantly more tests.

Feed Your Mind

1. Excited to launch #FeedYourMind today with @USDA & @EPA, to help you better understand everyday foods created with genetic engineering (also called GMOs). [hyperlink][image]
2. Genetic engineering has created new plants that are resistant to insects and diseases, led to products with improved nutritional profiles & certain produce that don’t brown/bruise as easily.
Hi Michael,

Please work to identify high level FDA needs to communicate to the HHS COVID19 Response-Alignment of OPDIV/STAFDIV Efforts (One pager – bulleted- bucketed). We can also highlight areas in which we are already working with our interagency partners (b)(5).

Thanks,

Denise
Good morning,

Attached please find the IMG Daily OpTempo, a combined meetings list, and IMG organizational structure, TF and distribution lists for reference.

We’ll need to revise to capture the QC-Commissioner Comms component within the AEG.

Thank you,

Denise
Hi,

Attached for your situational awareness is the 03 March FDA 2019-nCoV SITREP.

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

Many thanks for your continued support. -Michael


From: McWilliams, Carly [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=868C7458214244D08424FD441FEA4FDA-CARLYL.MCW]
Sent: 3/4/2020 11:29:30 AM
To: Lenihan, Keagan [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOBF23SPDLT)/CN=Recipients/CN=950c32cebc4b4f80b302c0f31c8524-Keagan.C]
Subject: RE: TP FOR VP at test developer roundtable
Attachments: Hahn_diagnostic-roundtable_3.4.20_cleared.docx

Cleaned up attached.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 11:26 AM
To: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: FW: TP FOR VP at test developer roundtable

Can you clean up and get to Frank/Colin for him? He is leaving in a few mins.

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 11:18 AM
To: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: TP FOR VP at test developer roundtable

Thanks Stephanie, suggestions from OCC attached – please reach out to Claire and Marcy if you have questions or concerns.

Thanks,
Dinesh

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 10:50 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: TP FOR VP at test developer roundtable

Thanks Stephanie, suggestions from OCC attached – please reach out to Claire and Marcy if you have questions or concerns.

Thanks,
Dinesh
Hi—
We may need some brief opening remarks for Dr. Hahn at this roundtable. Do these look ok?

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Wednesday, March 04, 2020 9:35 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: RE: TP FOR VP at test developer roundtable

(b)(5)

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:35 AM
To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: TP FOR VP at test developer roundtable

Good Morning,

We need to send in this morning, it is possible to get these cleared by 10am?

(b)(5)

Thank you in advance! As a heads up, we were also asked to look at information about (b)(5) and discuss at the 4pm VP meeting so cdr is developing talking points and I will send for clearance as soon as I receive them.

Appreciate all of your help!

Carly
Can you please review asap. Highlighted is new. I need to get to commissioner asap.
From: McWilliams, Carly [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHF23SPDLT)/CN=RECIPIENTS/CN=B68C7458214244D08424FD41FEA4FADA-CARLYLE.MCW]
Sent: 3/4/2020 4:31:29 PM
CC: Olivia, Frank [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOHF23SPDLT)/CN=Recipients/CN=180721db774423f9990dd86e67057c-Frank.Oliva]; Sheehy, Janice [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOHF23SPDLT)/CN=Recipients/CN=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Copeland, Jake [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOHF23SPDLT)/CN=Recipients/CN=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: FW: TPs for today
Attachments: 2020.03.04_WHTF_TPs_v3.docx

From: Caccamo, Stephanie
Sent: Wednesday, March 4, 2020 4:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: TPs for today
From: Carter, Lionel <Lionel.Carter@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 6:45 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Koerner, Harold <Harold.Koerner@fda.hhs.gov>
Subject: COVID19 CONPLAN

Hello Admiral Hinton

Here is the Coronavirus Disease 2019 Outbreak (COVID19) Concept of Operations Plan. We will probably need a technical editor to run through it quickly also, however the text has been updated based on the reviews that were able to be undertaken today by the IMG. I'd recommend that it be sent through the Offices/Centers (AEG) for a scrub and then we can finalize. It is also recommended we conduct that review via a SharePoint site. However if you prefer a different method we are certainly amenable to it. Apologies for the delay, however we wanted to make sure to address all comments.

V/r

Lionel Carter Acting Director
Office of Security and Emergency Management
10903 New Hampshire Avenue, WO32- RM1353
Silver Spring, MD 20993
PH:301-796-2796 | Mobile: (b)(6)
Lionel.Carter@fda.hhs.gov
Good evening RADM Orsega,

I believe this has already been addressed. I'm happy to speak by phone at any time to discuss details.

V/r,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

Please advise.

Regards,

Susan M. Orsega
Rear Admiral, Commissioned Corps Headquarters Director
United States Public Health Service
Office of the Surgeon General /US Department of Health and Human Services

Email: susan.orsega@hhs.gov
Subject: URGENT: Coronavirus request from FDA/CDER/OND

Importance: High

Hello Ma'am,

I am reaching out on behalf of leadership in Office of New Drugs (OND) in CDER/FDA. We have received a CC officer request from high up in the US Government that we urgently need to discuss with you.

Would you please call Khushboo Sharma's office at 301-796-1270 as soon as you are able? Ms. Sharma is OND’s Deputy Office Director for Operations.

Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service
Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience
Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-1160
Jacqueline.ware@fda.hhs.gov

U.S. FOOD & DRUG ADMINISTRATION

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Absolutely!

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:09 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Goldman, David <David.Goldman@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Kerns, Brook <Brook.Kerns@fda.hhs.gov>

Subject: RE: Update!

Respectfully,

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

Desk: 301-796-5205
Cell: (b)(6)
From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 7:59 PM
To: Goldman, David <David.Goldman@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: RE: Update: (b)(5) (RE: URGENT: Coronavirus request from FDA/CDER/OND)

Based off specific subject matter expertise – what a great opportunity!

From: Goldman, David <David.Goldman@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 7:55 PM
To: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: Re: Update: (b)(5) (RE: URGENT: Coronavirus request from FDA/CDER/OND)

Thank you—do we know why the name-request?

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Date: March 4, 2020 at 6:19:03 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Goldman, David <David.Goldman@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>, Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: FW: Update: (b)(5) (RE: URGENT: Coronavirus request from FDA/CDER/OND)
Importance: High

Passing the FDA PHS leadership for awareness!

(b)(5)

Respectfully,

Andrei Nabakowski, PharmD
Update: I spoke directly with Khushboo Sharma (CDER OND Deputy Director for Operations) who confirmed that a

Keagan Lenihan and Jim Sigg are reportedly aware and working the logistics

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: (b)(6)

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:47 PM
To: Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Andrei – hi – can you get in touch with Khushboo Sharma’s office below at 301-796-1270 to assist w/an urgent request thx

From: Zablan Jr., Russell <Russell.Zablan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:40 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Michael and Tom,

Please see the “urgent” request below from CDER.

Russell Zablan
Emergency Coordinator
Office of Emergency Operations (OEO)
Office of Emergency Management (OEM)
U.S. Food and Drug Administration
Duty Station: Atlanta, GA
Office: 404-253-2264
Blackberry (b)(5)
Email: russell.zablan@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:36 PM
To: FDA Emergency Operations <emergency.operations@fda.hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

From: Ware, Jacqueline H
Sent: Wednesday, March 04, 2020 5:22 PM
To: Orsega, Susan (OS) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Subject: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Hello Ma’am,

I am reaching out on behalf of leadership in Office of New Drugs (OND) in CDER/FDA. We have received a CC officer request from high up in the US Government that we urgently need to discuss with you.
Would you please call Khushboo Sharma’s office at 301-796-1270 as soon as you are able? Ms. Sharma is OND’s Deputy Office Director for Operations.

Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service
Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience

Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel 301-796-1160
Jacqueline.ware@fda.hhs.gov
Talking points

Begin forwarded message:

From: "Tantillo, Andrew" <Andrew.Tantillo@fda.hhs.gov>
Date: March 4, 2020 at 6:21:00 PM EST
To: "Shah, Anand" <Anand.Shah@fda.hhs.gov>
Cc: "Gross, Karas" <Karas.Gross@fda.hhs.gov>, "Paulos, Lauren" <Lauren.Paulos@fda.hhs.gov>
Subject: RE: Briefings Tomorrow

Apologies, omitted a bullet in the reactive. Updated version attached here.

From: Tantillo, Andrew
Sent: Wednesday, March 4, 2020 6:19 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Gross, Karas <Karas.Gross@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>
Subject: Briefings Tomorrow

Dr. Shah-

Attached are your proposed talking points for a statement, and some responses in the event you are asked about the topics we discussed today.
The first briefing is at 8:00am in room 419A of the Dirksen Senate Office Building. You will ride over from Humphrey in the ASL car with your fellow presenters. If for some reason you do not, it is a short cab ride from HHS, and you can enter Dirksen via the door at First St. & Constitution St., NE and proceed to the 4th floor. Either way Lauren Paulos and I will meet you outside the briefing room.

The second briefing is at 9:15am in the Capitol Visitor Center Auditorium. We will walk over with the HHS party.

Thank you for your willingness to do this on short notice. My cell number is [redacted] if anything comes up or you need anything.

Andrew Tantillo  
Deputy Director  
Office of Legislation  
U.S. Food and Drug Administration  
301-796-5810  
andrew.tantillo@fda.hhs.gov
Thanks for this info. Indeed an honor to be asked to contribute in this way.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: (b)(6)
From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 7:59 PM
To: Goldman, David <David.Goldman@fda.hhs.gov>; Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>; Anderson, Randy <Randy.Anderson@fda.hhs.gov>; Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: RE: Update: deployment of LCDR Gentles to Seattle per White House request to CDER/OND (RE: URGENT: Coronavirus request from FDA/CDER/OND)

Based off specific subject matter expertise – what a great opportunity!

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Date: March 4, 2020 at 6:19:03 PM EST
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Goldman, David <David.Goldman@fda.hhs.gov>, Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>, Jones, Estella <Estella.Jones@fda.hhs.gov>, Tarver, Darian B. <Darian.Tarver@fda.hhs.gov>, Anderson, Randy <Randy.Anderson@fda.hhs.gov>, Kerns, Brook <Brook.Kerns@fda.hhs.gov>
Subject: FW: Update: deployment of LCDR Gentles to Seattle per White House request to CDER/OND (RE: URGENT: Coronavirus request from FDA/CDER/OND)
Importance: High

Passing the FDA PHS leadership for awareness:

Respectfully,

Andrei Nabakowski, PharmD
Update: I spoke directly with Khushboo Sharma (CDER OND Deputy Director for Operations) who confirmed that a (b)(5) Keagan Lenihan and Jim Sigg are reportedly aware and working the logistics (b)(5)

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
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Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Importance: High

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Sent: Wednesday, March 4, 2020 5:40 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Cc: Russo, Mark <Mark.Russo@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>; FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND

Importance: High

Michael and Tom,

Please see the “urgent” request below from CDER.

Russell Zablan
Emergency Coordinator
Office of Emergency Operations (OEO)
Office of Emergency Management (OEM)
U.S. Food and Drug Administration
Duty Station: Atlanta, GA
Office: 404-253-2264
Blackberry: (b)(5)
Email: russell.zablan@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:36 PM
To: FDA Emergency Operations <emergency.operations@fda.hhs.gov>

Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND

Importance: High

From: Ware, Jacqueline H
Sent: Wednesday, March 04, 2020 5:22 PM
To: Orsega, Susan (OS) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>

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Importance: High

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Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service
Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience
Deputy Director (acting)
Office of Regulatory Operations
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel 301-795-1160
Jacqueline.ware@fda.hhs.gov

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Noted – thank you, Khushboo.

Hello,

I appreciate all your help.

Khushboo Sharma, MBA, RAC
Deputy Office Director of Operations
Office of New Drugs
Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-796-1270 Cell: 503-546-3507
Khushboo.sharma@fda.hhs.gov

Good evening, CAPT Ware,

Thank you for the note. I am copying RADM Hinton to see if there is any information that may assist in this request.

V/R
From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:22 PM
To: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo (FDA/CDER) <Khushboo.Sharma@fda.hhs.gov>
Subject: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

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Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service
Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience
Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 301-795-1160
Jacqueline.ware@fda.hhs.gov

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Thank you- understood, ma'am.

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
Cell: [b](6) [b](6)

OT5 | Office of Talent Solutions
U.S. FOOD & DRUG ADMINISTRATION

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:56 PM
To: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

From: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 8:53 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

(b)(5)

Per OND with Jim Sigg and Keagan Lenihan engaged and being worked. I have not spoke directly with either of them to confirm, but trust the CDER Ops DD and the loop would be closed.

I could reach out to Jim to verify (just let me know)

Respectfully,

Andrei Nabakowski, PharmD
Captain, U.S. Public Health Service
Director, FDA Commissioned Corps Affairs
FDA Agency Liaison
Andrei.Nabakowski@fda.hhs.gov
Desk: 301-796-5205
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Sent: Wednesday, March 4, 2020 8:51 PM
To: Nabakowski, Andrei <Andrei.Nabakowski@fda.hhs.gov>
Subject: FW: URGENT: Coronavirus request from FDA/CDER/OND

Loop is closed – correct?

From: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Sent: Wednesday, March 4, 2020 8:49 PM
To: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Sharma, Khushboo <Khushboo.Sharma@fda.hhs.gov>
Subject: RE: URGENT: Coronavirus request from FDA/CDER/OND

Good evening, CAPT Ware,

Thank you for the note. I am copying RADM Hinton to see if there is any information that may assist in this request.

V/R

Regards,

Susan M. Orsega
Rear Admiral, Commissioned Corps Headquarters Director
United States Public Health Service
Office of the Surgeon General /US Department of Health and Human Services

From: Ware, Jacqueline H <Jacqueline.Ware@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 5:22 PM
To: Orsega, Susan (OS/OASH) <Susan.Orsega@hhs.gov>
Cc: Sharma, Khushboo (FDA/CDER) <Khushboo.Sharma@fda.hhs.gov>
Subject: URGENT: Coronavirus request from FDA/CDER/OND
Importance: High

Hello Ma’am,

I am reaching out on behalf of leadership in Office of New Drugs (OND) in CDER/FDA. We have received a CC officer request from high up in the US Government that we urgently need to discuss with you.
Would you please call Khushboo Sharma’s office at 301-796-1270 as soon as you are able? Ms. Sharma is OND’s Deputy Office Director for Operations.

Very respectfully,
CAPT Ware

Jacqueline H. Ware, Pharm.D.
Captain, United States Public Health Service
Chief, Project Management Staff, Neurology 1 (acting) and Neurology 2
Division of Regulatory Operations for Neuroscience

Deputy Director (acting)
Office of Regulatory Operations

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel 301-796-1160
Jacqueline.ware@fda.hhs.gov
From: Hinton, Denise (O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
To: Hebert, Angelique A. (O=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]
Subject: FYSA: draft inspection statement
Attachments: draft_inspection_3.4.20_915pm.docx

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 9:16 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: draft inspection statement

DRAFT DELIBERATIVE CONFIDENTIAL
Lionel,

I agree with the approach in conducting reviews via SharePoint – this will help with version control. Please confirm whether this has been reviewed by the IMG and if each Center/ORA has had an opportunity to review/comment. Either way, it can still be sent to the AEG for awareness. A goal would be to provide a briefing to the AEG/Commissioner in the EOC as early as possible next week after the Commissioner completes his budget hearing. Make sense?

Thanks,

Denise

V/r

Lionel Carter Acting Director
Office of Security and Emergency Management
Thanks.

Agreed. As a first step, I’ve reached out to Anand. I’ve also been updating CDER. I next need to reach out to ASPR. But, agreed, I think an internal discussion is needed (including Center leadership and OCC).

Probably needs a discussion.
Hi Keagan,

CDER (Johanna McLatchy) might already have contacted you about this. I just spoke with CDER about the attached RFI they’ve drafted.

(b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

---

From: Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Sent: Thursday, March 05, 2020 9:51 AM
To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning <2019-nCoVFDAIMGPlanning@fda.hhs.gov>
Cc: CDER-ER-OPS <CDEREROPS@fda.hhs.gov>; CDER COVID-19 Response <CDERCOVID19Response@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Throckmorton, Douglas C <Douglas.Throckmorton@fda.hhs.gov>; Bernstein, Jessica <Jessica.Bernstein@fda.hhs.gov>
Subject: RFI to ASPR

Operations/Planning,

CDER asks that you send the attached memo to Dr. Kadlec at ASPR. CDER is requesting ASPR to create a list of approved drugs and therapeutic biologics that are being used to manage patients with COVID-19.

Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead
Keagan – if his calendar allows, we can use the time immediately following

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:21 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

This is potentially something we could discuss on Tuesday morning with CDs and Dept Commish.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:09 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 12:53 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

We could consider partnering, but maybe we need to discuss further because there are some internal concerns about fda developing such lists for interagency use, and also agreement that ASPR is probably better positioned to get a fuller, more accurate picture of what’s “important” or “priority” from the manufacturer groups, clinician/health care community level, etc. Happy to talk more.
I just sent you her email. I agree it should be ASPR, but we have a way bigger team and better access to these companies, right? Can we partner?

Hi Keagan,

Thoughts on how best to proceed?

Thanks so much,
Brooke

Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead
From: Lenihan, Keagan [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFDS21B0105D17D2-KEAGAN.LENI]
Sent: 3/5/2020 3:35:45 PM
To: Courtney, Brooke [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=261a2a3791e24e19b095ac0172485ebd-Brooke.Cour]; Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c8b5adb-HINTOND]
CC: Mair, Michael [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=f451bdad7564d7e7c7e70c7961467ab-Michael.Mai]
Subject: RE: RFI to ASPR

Maybe next week.

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Subject: RE: RFI to ASPR

Maybe AEG tomorrow.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, March 5, 2020 3:32 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Keagan – if his calendar allows, we can meet following the check-in on Tuesday (0915) or the AEG w/principals or their one designee to keep small for discussion.

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Subject: RE: RFI to ASPR

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: March 5, 2020 at 12:48:35 PM EST
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

(b)(5)

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 5, 2020 10:45 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Thoughts on how best to proceed?

Thanks so much,
Brooke

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Let me know if you have questions.

Rosemary Roberts
COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead
Hi! I went through yesterday's sit rep and re-ordered some things to make the most pertinent information up top. Just suggestions with the goal of making Michael’s life a little easier.

Denise, give me a ring when you can so we can touch base
Good progress. Thanks Brooke.

Also, a quick update that I just spoke with Laura Wolf/ASPR to coordinate. She’s in the process of planning a meeting with industry (e.g., PhRMA, BIO, AAM) for tomorrow to try to get a sense from them what products might be of priority for them. Also, over the summer, a list of 100 essential meds was developed by the private sector, so Laura is pulling that up. This is all to try to inform ASPR and FDA’s development of a list, if that’s still the plan after talking with leadership next week. Finally, Anand and I are schedule to talk at 5 today.

Thank you, I can be available either of those times (9:15, noon) and both days. I arrive around 7:30 and will make any time work.

We can dedicate time to discuss during Monday’s or Tuesday’s noon AEG meeting or immediately following the commissioner check-in at 0915. Keagan -let us know if you have a preference. Brooke – please state your availability on either day. Thanks

Maybe next week.
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Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: RFI to ASPR

Probably needs a discussion.
From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
Sent: Thursday, March 5, 2020 10:45 AM  
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>  
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
Subject: FW: RFI to ASPR

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CDER (Johanna Mclatchy) might already have contacted you about this. I just spoke with CDER about the attached RFI they've drafted. (b)(5)

Thoughts on how best to proceed?

Thanks so much,
Brooke

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Sent: Thursday, March 05, 2020 9:51 AM  
To: 2019-nCoV FDA IMG Operations <2019-nCoVFDAIMGOperations@fda.hhs.gov>; 2019-nCoV FDA IMG Planning
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CDER asks that you send the attached memo to Dr. Kadlec at ASPR. CDER is requesting ASPR to create a list of approved drugs and therapeutic biologics that are being used to manage patients with COVID-19.

Let me know if you have questions.

Rosemary Roberts

COVID-19 Outbreak Response, FDA IMG Operations, Drugs Lead
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHBF23SPDLT)/CN=RECIPIENTS/CN=85FECA08E0694803BE6030E97C7B4ADB-HINTOND]
To: Hebert, Angelique A. [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOHBF23SPDLT)/CN=Recipients/cn=9aa08f3428a045f88eb3bd92c68a27cf-Angelique.H]
Subject: RE: For early review: Draft all hands email message from Dr. Hahn to staff on COVID 19 updates
Attachments: SMH all hands update on COVID 3.5.2020_OO.docx

From: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:43 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: For early review: Draft all hands email message from Dr. Hahn to staff on COVID 19 updates

Whatttttt

From: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>
Sent: Thursday, March 5, 2020 4:36 PM
To: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Tse, Tania <Tania.Tse@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>
Subject: For early review: Draft all hands email message from Dr. Hahn to staff on COVID 19 updates

Hi all,

Laura suggested I share this draft all-hands message with you for review ASAP today. Please let us know by 6:00 p.m. if possible if you have any edits or comments. Then I will share with the JIC. Specifically flagging your preference on where to refer people who have travel questions.

Thank you.

Sandy Walsh
Acting Director
Office of Editorial and Creative Services
Office of External Affairs
U.S. Food and Drug Administration
Tel: 301-796-4669
Sandy.Walsh@fda.hhs.gov
Good evening,

Passing along the OCC cleared version of the COVID-19 health fraud warning letters press release. I will be flagging for HHS momentarily.

Please let me know of any concerns or edits by 11:59pm.

Heidi/Laura- can this be flagged for the commissioner’s review tonight?

We expect to go out with this sometime after 12pm tomorrow when the warning letters are ready for posting.

Please let me know if there are any questions.

Thank you,
--Jeremy

Jeremy Kahn
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-796-8671
jeremy.kahn@fda.hhs.gov
Hi – some ideas. Use whatever works m

DRAFT, DELIBERATIVE, CLOSE HOLD
Thank you,
Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1956
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov
From: MacLennan, Lori [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDI BO HF 23SPDL T)/CN=RE Cl Pl ENTS/CN = 7E3684D6A36E4002BC07015B75068803-LORI.MACLE N]
Sent: 3/6/2020 11:12:44 AM
CC: re: JIC AEG Review Requested by COB Today, Mar 4: APPhA Coronavirus Emergency Responders-CDER
Subject: + Jim Sigg (mistakenly included Linda Sigg in previous email)

+ Checking on status – is this cleared?

Thank you!
Lori

From: MacLennan, Lori
Sent: Wednesday, March 4, 2020 10:43 AM
To: Sigg, Linda A <Linda.Sigg@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Finnen, April <April.Finnen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Delancey, Siobhan <Siobhan.Delancey@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: JIC AEG Review Requested by COB Today, Mar 4: APPhA Coronavirus Emergency Responders-CDER

Hi,

Requesting AEG clearance on a CDER-cleared journal article, which has been cleared by the JIC/IMG and OCC. The short article (750 words) is intended for publishing in the Journal of the American Pharmacists Association and is highly supported by CDER leadership to highlight the coronavirus response work of CDER’s PHS officers. Can you please review the attached text article on SharePoint by COB today, Wed, Mar 4?

Text included below for quick reference:

Novel Coronavirus Emergency Responders in FDA’s Center for Drug Evaluation and Research
LCDR Andrea Gormley, PharmD, JD
CDR Kelly Ngan, PharmD, MPH, CPH

FDA-OSJI-FOIA-2020-3541_00004963
United States Public Health Service\(^{[1]}\) (USPHS) pharmacist officers in the Food and Drug Administration’s (FDA) Center for Drug Evaluation and Research (CDER) are actively engaged in the 2019 novel coronavirus disease (COVID-19) response. These officers are trained to stand ready, engaging in a moment’s notice for any new CDER emergency response. Pharmacist officers currently serve in “Incident Command System” positions such as Operations Section Chief and Planning Section Chief on CDER’s official coronavirus (SARS-CoV-2) response task force. In these positions, they coordinate subject matter expert teams responding to urgent requests for information from federal government partners, including the Health and Human Services’ Assistant Secretary for Preparedness and Response (ASPR) and Centers for Disease Control and Prevention (CDC). They assist in preparing CDER statements for the FDA Commissioner and legislative briefings to keep stakeholders informed of COVID-19 response activities.

There are currently no approved drug products for the prevention or treatment of COVID-19. Pharmacist officers are serving as Emergency Coordinators working directly with physicians of U.S. COVID-19 patients to enable access to investigational drugs for treatment under emergency Investigational New Drug (eIND) processes. These officers are on-call 24/7 to ensure health care providers across the U.S. can access FDA staff at any time to facilitate the use of investigational drugs when the patients they are treating have exhausted all approved drug product options.

With the globalization of the pharmaceutical supply chain, FDA is tasked with closely monitoring events that could threaten the U.S. supply of drug products. As part of the COVID-19 emergency response, CDER Drug Shortage Staff (DSS) pharmacist officers are actively monitoring drug supply chains related to components manufactured in China to anticipate and mitigate any drug product shortages resulting from manufacturing disruptions from the outbreak. Drug shortage situations can negatively impact patient care and challenge the tools available to health care providers, making this proactive supply chain monitoring a critical component of FDA’s emergency response. DSS maintains frequent communication with manufacturers to help prevent drug shortages. As a resource for the public, FDA maintains a website for real-time information about drug shortages here: https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm.

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During emerging infectious disease outbreaks, FDA must be vigilant to protect the public from fraudulent products falsely claiming to prevent or treat COVID-19. Pharmacist officers contribute to FDA’s task force dedicated to closely monitoring for fraudulent products and false product claims related to COVID-19. During public health emergencies, FDA is committed to identifying and taking regulatory action against products that mislead the public in the prevention or treatment of emerging infectious diseases.

Providing up-to-date information to the public is a critical component of emergency response. In CDER, pharmacist officers participate in FDA-wide communications teams charged with issuing key information for the public about the current outbreak. These officers developed a webpage that provides information about treatment options, fraudulent products, and FDA’s emergency response resources. This team also has pharmacist officers in the Division of Drug Information (DDI) who answer direct questions from the public about coronavirus.

These examples provide a snapshot of the myriad responsibilities and duties of USPHS pharmacist officers at the FDA during a global public health emergency response. These pharmacist officers work tirelessly during emergencies such as COVID-19 to complete the mission: protecting public health by ensuring U.S. citizens have access to safe, effective, quality and available drug products.

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Acknowledgments: The authors gratefully acknowledge the following USPHS pharmacist officers for their FDA service and contributions to this article: CAPT Andrei Nabakowski, CAPT Val Jensen, CAPT Mary Kremzner, CAPT Paras Patel, CDR Ray Ford, CDR Larry Lim, CDR Rebecca McKinnon, LCDR Lena Choe, LCDR Carlos Gonzalez-Mercado, LCDR Gayle Tuckett, LT Renu Lal.

Initial CDER Document Clearance History:
Initial Draft, CDER CTECS (AGormley, KNgan): 2/13/20
Edits, cleared CDER DDI (MKremzner, LChoe): 2/14/20
Edits, cleared CDER DSS (VJensen, PPatel): 2/14/20
Edits, cleared CDER CTECS (AGormley, KNgan, RRoberts): 2/16/20
Cleared, CDER OCD (DThrockmorton): 2/17/20
Cleared, FDA Commissioned Corps Affairs-FCCA (ANabakowski): 2/19/20

Document History (JIC/IMG)

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From: MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 10:15 AM
To: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: OCC Clearance (JIC FYI) Requested by 9am Wed, Mar 4: APhA Coronavirus Emergency Responders-CDER

Great, thank you!

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Wednesday, March 4, 2020 10:11 AM
To: MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: OCC Clearance (JIC FYI) Requested by 9am Wed, Mar 4: APhA Coronavirus Emergency Responders-CDER

Hi Lori - clearing for OCC without change.

Thanks,
Dinesh

From: MacLennan, Lori <Lori.MacLennan@fda.hhs.gov>
Sent: Tuesday, March 3, 2020 2:38 PM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Subject: OCC Clearance (JIC FYI) Requested by 9am Wed, Mar 4: APhA Coronavirus Emergency Responders-CDER

Hi,

Requesting OCC clearance (and sending to JIC as an FYI) on a CDER-cleared journal article. The short article (750 words) is intended for publishing in the Journal of the American Pharmacists Association and is highly supported by CDER leadership to highlight the coronavirus response work of CDER’s PHS officers. Can you please review the APhA Coronavirus Emergency Responders article on SharePoint by 9am, Wed, Mar 4?

Text included below for quick reference:

Novel Coronavirus Emergency Responders in FDA’s Center for Drug Evaluation and Research
LCDR Andrea Gormley, PharmD, JD
CDR Kelly Ngan, PharmD, MPH, CPH
United States Public Health Service (USPHS) pharmacist officers in the Food and Drug Administration (FDA) Center for Drug Evaluation and Research (CDER) are actively engaged in the 2019 novel coronavirus disease (COVID-19) response. These officers are trained to stand ready, engaging in a moment’s notice for any new CDER emergency response. Pharmacist officers currently serve in “Incident Command System” positions such as Operations Section Chief and Planning Section Chief on CDER’s official coronavirus (SARS-CoV-2) response task force. In these positions, they coordinate subject matter expert teams responding to urgent requests for information from federal government partners, including the Health and Human Services’ Assistant Secretary for Preparedness and Response (ASPR) and Centers for Disease Control and Prevention (CDC). They assist in preparing CDER statements for FDA Commissioner and legislative briefings to keep stakeholders informed of COVID-19 response activities.

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Thank you!
Lori

Lori MacLennan
Health Communications Specialist, External Communication Branch
CDRH Communications

2019 Novel Coronavirus (COVID-19) Joint Information Center (JIC)

Center for Devices and Radiological Health (CDRH)
Office of Communication and Education
Division of Communication
U.S. Food and Drug Administration
Tel: 240-402-0562
lori.maclennan@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.
Please see attached COVID-19 guidance from VA on the protection of Veterans and staff for Community Living Centers.

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

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Subject: COVID-19 PMO Call

When: Friday, March 6, 2020 11:15 AM-12:15 PM (UTC-05:00) Eastern Time (US & Canada).

Where: 610F/Dial In Below

(b)(6) (b)(6)

<< File: HHS COVID-19 PMO Description_FINAL.pdf >> << File: COVID-19 HHS PMO Daily Sync Call Agenda.docx >>
And here are reactive responses

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From: Tantillo, Andrew
Sent: Friday, March 6, 2020 1:34 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Paulos, Lauren <Lauren.Paulos@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; Tomasello, Jennifer <Jennifer.Tomasello@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: Remarks for Hill Call at 1:50
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Administrative Group [FYDIBOHF23SPDLT]/cn=Recipients/cn=e20544000bb4629be1facce0846fc-HHS-Judy.St];
Good afternoon everyone,

Here is today’s COVID-19 daily guidance update. As always, if you see something that needs to be changed or want to add something, please do not hesitate to contact myself or CAPT Perdue.

This guidance update is being sent out to the PMO list and others by request.

Hope you all enjoy the weekend

Very respectfully,

Will

William Farmer, MS
Presidential Management Fellow - Program Analyst
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements
Division of Requirements

HEALTH AND HUMAN SERVICES (HHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
Office: (202) [b][6] Mobile: [b][6]
william.farmer@hhs.gov | www.phe.gov
CC: Bishop, Ralph (SAMHSA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4c8f3e480eb4f0a9777d295075fad22-HHS-Christi]; Watson, Ryan (SAMHSA) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f9e736246da84828b8d23db604f88269-HHS-Ralph.B]; Thornton, Cody R (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e954c51879cfe4cbb28dd497043cd56ea-HHS-Ryan.Wai]; Cote, Mick Charles (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e69ee27dc37974ab99e0465663d21222da-HHS-Code.Th]; Cote, Mick Charles (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ecd636c2d85c4a00a8d822bb3b8c6e8-HHS-Mick.Coj]; Lawrence, Theresa (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b76a0d2fc644dd2b521385fe423af7-HHS-Theresa]; Hadzibegovic, Diana S (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=20a790bb18a646ed92a3dd40eb4c316-HHS-Diana.H]; Donato, Darrin (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=59880927cd1c4c54898474f90a3cf036-HHS-Darrin.]; Moughalian, Jen C (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1227fced76ad4092bb5f1395d24c0d74-HHS-Jen.Moul]; Colf, Leremy (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=02993559395b41a936c91cc36fa5da0-HHS-Matthew]; Mair, Michael (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mail]; awang@usaid.gov; Ignacio, Joselito (FEMA.DHS.GOV) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82bb994c24a34b1bb5bd335f44389c02-HHS-Shante.]; Houchens, Christopher (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7fd780651964b4bb9999a9865886b23-HHS-Christo]; Newland, Matthew J (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=851a027f41674e5ab745c7b5edd-HHS-Sandra.]; Holland, Tara (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=71330f3f6a5c4a669bcd05ce657d7d5b5-HHS-Tara.Ho]; Dafflitto, Scott (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64a942e3099d434ba6aa8fe2471b8191-HHS-Scott.D]; Hall, Bill (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4e56218361cd4ffbacdd06ac2d7b809d-HHS-bill.ha]; Jackson, Zhoowan (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03bb8af5a37f14499b9c1112479ed7a6f-HHS-Zhoowan]; Krohmer, Jon (dot.gov) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=221e456c54184f89f0651e886f4310-HHS-Patrici]; Oshansky, Christine (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da126c25ca04db922973cd7cbb459-HHS-Ruben.D]; Cormier, Justin P (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6ab274ee2c8341f39d7ee4a9a1ecf405-HHS-Christi]; Cabezas, Miriam (OS) /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b45d63ce4e714998aeb255ef0e4a5-HHS-Miriam.]

Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting; Canceled: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment
Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials
Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)
If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Canceled: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment

Location: Conference Number: (b)(6) ; Access Code: (b)(6)

FDA-OSJI-FOIA-2020-3541_00004854
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Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
Subject: COVID-19 Daily Disaster Leadership Group Meeting

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Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O'Neill House Office Building | 200 C Street SW | Washington, DC 20515
a. (202) (b)(6)
Daniel.Dodgen@HHS.Gov | www.phe.gov
Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Number: (b)(6) Access Code: (b)(6)
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Read Ahead Materials

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Conference Line

Conference Number: (202) (b)(6)  
Meeting Access Code: (b)(6)
If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy DLGDESK@hhs.gov.

Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS)  O’Neill House Office Building  200 C Street SW  Washington, DC 20515

Daniel.Dodgen@HHS.Gov  www.phe.gov
Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment

Location: Conference Number: (b)(6) Access Code: (b)(6)
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HEALTH AND HUMAN SERVICES (DHHS) | O’Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) (b)(6)
Daniel.Dodgen@HHS.Gov | www.phe.gov
COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

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Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
COVID-19 Daily Disaster Leadership Group Meeting

Attachments:
COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment

Location: Conference Number: (b)(6) Access Code: (b)(6)

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Dear Disaster Leadership Group (DLG) Members:

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Conference Line

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o. (202) (b)(6)
Daniel.Dodgen@HHS.Gov | www.phe.gov
COVID-19 Daily Disaster Leadership Group Meeting

From: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]
Sent: 3/6/2020 6:49:16 PM
To: DLGDESK (HHS/ASPR/OPP) [DLGDESK@hhs.gov]; Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinse (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OHMA HQ); McDaniell, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCHHSTP/DASH); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosoa, Diana (HRSA); Macrae, Jim (HRSA); Weahkeek, Michael (HHS/HQ); McCollum, Jeffrey T (HHS/HQ); Frazier, Francis (HHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillipse, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/EMMO); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbarelle, Samuel (OS/ASPR/OSIM); DeBord, Kristin (OS/ASPR/SPPR); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/OSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Getttinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dashker, David (HHS/ASFR); Rachel Kellogg (HHS/OS)

Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Numbers (b)(6) Access Code (b)(6) Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

Start: 3/9/2020 3:00:00 PM
End: 3/9/2020 4:00:00 PM
Show Time As: Busy

Recurrence: Daily every weekday from 3:00 PM to 4:00 PM

Required Attendees: Haris, Mariam (OS/ASPR/SPPR) (CTR); Fucci, Michael (OS/ASPR/SPPR) (CTR); Donnelly, Kelsey (OS/ASPR/SPPR) (CTR); Roman-Stolte, Claudia (OS/ASPR/SPPR) (CTR); Stannard, Paula (HHS/IOS); Mango, Paul (HHS/IOS); Agnew, Ann (HHS/IOS); Trueman, Laura (HHS/IEA); Kadlec, Robert (OS/ASPR/IO); Bird, Catherine (OS/OGC); Hittle, Taylor (HHS/ASFR); Arbes, Sarah (HHS/ASL); Bradsher, Kris (HHS/ASL); Murphy, Ryan (OS/ASPA); Destro, Brenda (HHS/ASPE); Nevel, Amy (HHS/ASPE); Tobias, Constance (HHS/DAB); Giroir, Brett (HHS/OASH); Schwartz, Erica (HHS/OASH); Severino, Roger (HHS/OCR); Bell, March (HHS/OCR); Frohboese, Robinse (HHS/OCR); Grigsby, Garrett (HHS/OS/OGA); Kerr, Lawrence (HHS/OS/OGA); Chang, William (HHS/OGC); Taitsman, Julie K (OIG/IO); Griswold, Nancy (HHS/OHMA HQ); McDaniell, Eileen (HHS/OMHA); Rucker, Donald (OS/ONC); Chaput, Daniel (OS/ONC); Johnson, Lynn (ACF); Robertson, Lance (ACL); Nicholls, Richard (ACL); Phillips, Christine (ACL); Meyers, David (AHRQ/IOD); McNellis, Robert (AHRQ/CEPI); Patel, Anita (CDC/DDID/NCHHSTP/DASH); Ethier, Kathleen (CDC/DDID/NCHHSTP/DASH); Knutson, Donna (CDC/DDNID/NCEH/OD); Brookes, Brady (CMS/OA); Payne, Skip (CMS/OA); Blackford, Carol W. (CMS/CM); sh1@fda.hhs.gov; Hinton, Denise (FDA/OC); Cheever, Laura (HRSA); Espinosoa, Diana (HRSA); Macrae, Jim (HRSA); Weahkeek, Michael (HHS/HQ); McCollum, Jeffrey T (HHS/HQ); Frazier, Francis (HHS/HQ); Collins, Francis (NIH/OD) [E]; Fauci, Anthony (NIH/NIAID) [E]; Marston, Hilary (NIH/NIAID) [E]; McCance-Katz, Elinore (SAMHSA/OAS); Delvecchio, Paolo (SAMHSA/OMTO); Lobos, Elisa (SAMHSA/OFR/OD); Shuy, Bryan (OS/ASPR/IO); Yeskey, Kevin (OS/ASPR/IO); Bright, Rick (OS/ASPR/BARDA); Disbrow, Gary (OS/ASPR/BARDA); Lambert, Linda (OS/ASPR/BARDA); Phillipse, Sally (OS/ASPR/SPPR); Smith, Matthew (OS/ASPR/EMMO); Greene, Jonathan (OS/ASPR/EMMO); Cooper, Kevin (OS/ASPR/ORM); Imbarelle, Samuel (OS/ASPR/OSIM); DeBord, Kristin (OS/ASPR/SPPR); Gin, Julia (OS/ASPR/SPPR); Adams, Steven A. (CDC/SNS/OSNS); Lee, Scott (OS/ASPR/EMMO); Austin, Meredith (uscg.mil); Wolf, Laura (OS/ASPR/SIIM); Perdue, Christopher (OS/ASPR/SPPR); Herrmann, Jack (OS/ASPR/OEA); Johnson, Robert (OS/ASPR/BARDA); Wong, Diana (OS/ASPR/SIIM); Vineyard, Michael (OS/ASPR/IO); Mackay, Thomas (OS/ASPR/EEAA); Moudy, Robin (OS/ASPR/SPPR); Dodgen, Daniel (OS/ASPR/SPPR); Getttinger, Andrew (OS/ONC); Abbey, Rachel (OS/OSCP); Lennon, Todd (HRSA); Dashker, David (HHS/ASFR); Rachel Kellogg (HHS/OS)
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Meeting Logistics & Conference Line

Conference Number: (202) \textbf{(b)(6)}
Meeting Access Code: \textbf{(b)(6)}

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Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
Subject: COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Number [b](6)[b]
Access Code [b](6)[b]

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment

Start: 3/9/2020 3:00:00 PM
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COVID-19 Daily Disaster Leadership Group Meeting

Location: Conference Number: [access code] Room #: 624D.7 | Humphrey Building at 200 Independence Avenue SW, Washington DC, 20201

Start: 3/9/2020 3:00:00 PM
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Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment

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FDA-OSJI-FOIA-2020-3541_00004901
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Subject: COVID-19 Daily Disaster Leadership Group Meeting

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FDA-OSJI-FOIA-2020-3541_00004907
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Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
[o=ExchangeLabs/ou=Exchange Administrative Group]
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(ACL) [o=ExchangeLabs/ou=Exchange Administrative Group]
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(AHRQ) [o=ExchangeLabs/ou=Exchange Administrative Group]
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(CDC) [o=ExchangeLabs/ou=Exchange Administrative Group]
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(CMS) [o=ExchangeLabs/ou=Exchange Administrative Group]
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(SAMHSA) [o=ExchangeLabs/ou=Exchange Administrative Group]
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(SAMHSA) [o=ExchangeLabs/ou=Exchange Administrative Group]
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<th>Name</th>
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<tr>
<td>Bright, Rick</td>
<td>os@exchangelabs</td>
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<td>Disbrow, Gary</td>
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<td>Lambert, Linda</td>
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<td>Phillips, Sally</td>
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<td>Austin, Meredith</td>
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<td>Perdue, Christopher</td>
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<td>Dodgen, Daniel</td>
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<td>Kellogg, Rachel</td>
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<td>Bettencourt, Alice</td>
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<td>Cochran, Norris</td>
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<td>Bishop, Ralph</td>
<td>os@exchangebooks</td>
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*Note: All emails are associated with the FDA-OSJI-FOIA-2020-3541_00004911 project.*
Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Conference Number: (b) Access Code: (b)
Start: 3/9/2020 3:00:00 PM
Dear Disaster Leadership Group (DLG) Members:

The Office of the Assistant Secretary for Preparedness and Response (ASPR) will convene a daily DLG meeting. The purpose of these meetings is to resolve COVID-19 policy issues coming from the White House or from HHS Leadership. If you are aware of any critical policy issues that emerged during the day, please be prepared to discuss them with this group.

Read Ahead Materials
Read ahead materials will be added as an update to this invitation as early in the day as possible so that invitees have time to review prior to the meeting.

Conference Line

Conference Number: (202) (b)(6)
Meeting Access Code: (b)(6)

If you have any questions, please reach out to me Dan Dodgen (Daniel.Dodgen@hhs.gov) and kindly copy
Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O’Neill House Office Building | 200 C Street SW | Washington, DC 20515
a. (202)_____ (b)(6)_____
Daniel.Dodgen@HHS.Gov | www.phe.gov
Subject: COVID-19 Daily Disaster Leadership Group Meeting
Attachments: COVID-19 Daily Disaster Leadership Group Meeting; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment
Location: Conference Number (__b6__) Access Code: ___(b)(6)___
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Respectfully,

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O’Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) (b)(6)___
Daniel.Dodgen@HHS.Gov | www.phe.gov
Subject: COVID-19 Daily Disaster Leadership Group Meeting

Attachments: COVID-19 Daily Disaster Leadership Group Meeting ; Untitled Attachment; Untitled Attachment; Untitled Attachment; Untitled Attachment; Canceled: COVID-19 Daily Disaster Leadership Group Meeting

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Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O’Neill House Office Building | 200 C Street SW | Washington, DC 20515
o. (202) (b)(6)
Daniel.Dodgen@HHS.Gov | www.phe.gov
Yes – please see attached document. Tim did a great job today – so thankful he was on the line and helped respond to questions.

Denise,

You have a really well done overview of the diagnostics space.

Can you please send over your script? We want to repurpose some of it for WH Press Conference tomorrow which we were just asked to provide info for

Suzanne B. Schwartz, MD, MBA
Deputy Director (& Acting Office Director) Office of Strategic Partnerships & Technology Innovation (OST)
Center for Devices & Radiological Health
US Food & Drug Administration
Office: 301-796-6937
Mobile: 202-841-9996
From: Mair, Michael
(O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FA7C7EADC7961467AB-MICHAEL.MAIR)
Sent: 3/7/2020 9:39:07 AM
To: Hinton, Denise
(O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85fe0be0694803be603a97c7b4adb-HINTOND)
Subject: FW: Can you pls fw me the working draft
Attachments: press briefing talkers_3.7.20 840am_clean.docx

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 7, 2020 9:38 AM
To: Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Can you pls fw me the working draft

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Saturday, March 07, 2020 9:37 AM
To: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Can you pls fw me the working draft

So I can follow along... thx
FYI. As per discussion at Thursday's Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU's resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.
Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader
UCSF-Stanford CERSI Program Official (PO)
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 1, Rm 4220
Silver Spring, MD 20903
301-796-3520
Hello Colleagues,

Here is a one pager describing some Johns Hopkins’ resources that may be relevant to FDA’s COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc:d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH’s Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA’s response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexan@jhsph.edu
FYI. As per discussion at Thursday’s Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU’s resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.
Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader
UCSF-Stanford CERSI Program Official (PO)
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 1, Rm 4220
Silver Spring, MD 20903
301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>
Sent: Saturday, March 07, 2020 8:46 PM
To: Thomas, Audrey A <Audrey.A.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Smith, Tara (CDRH); Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: COVID19  
Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins’ resources that may be relevant to FDA’s COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc:d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH’s Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA’s response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS  
Johns Hopkins Bloomberg School of Public Health  
Center for Drug Safety and Effectiveness  
615 N. Wolfe Street, W6035  
Phone: (410) 955-8168  
Email: galexand@jhsph.edu
From: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov)
Sent: Sunday, March 8, 2020 7:23 PM
To: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Hinton, Denise (Denise.Hinton@fda.hhs.gov); Hebert, Angelique A. (Angelique.Hebert@fda.hhs.gov); Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov)
Subject: RE: HHS Call

FYSA SH cleared his message. I have sent to ASPA and then VP clearance. I noted that Jim’s mail was also submitted via Catherine Bird/ASA. My recommendation is that we send Dr. Hahn first, if possible, depending on how they come back. When you receive clearance, would you flag and I can check in on timing for SH. Will let you know when SH is cleared. If they aren’t stacked, we can reassess.

LMK if you concur.

From: Caliguiri, Laura
Sent: Sunday, March 8, 2020 7:09 PM
To: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Hinton, Denise (Denise.Hinton@fda.hhs.gov); Hebert, Angelique A. (Angelique.Hebert@fda.hhs.gov); Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov)
Subject: RE: HHS Call

Copy

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Sunday, March 8, 2020 10:04 PM
To: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Hinton, Denise (Denise.Hinton@fda.hhs.gov); Hebert, Angelique A. (Angelique.Hebert@fda.hhs.gov); Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov)
Subject: RE: HHS Call

Thanks Laura. Based on the call this evening, we should send the Commissioner’s message through ASA as well. If you get me the final version, I can send to Blair or you can if you want.

Thanks,
Jim

From: "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 8, 2020 9:42 PM
To: "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>, "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>, "Hebert, Angelique A." <Angelique.Hebert@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

Thanks Laura. Would you let know it has already been sent to ASPA.

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Sunday, March 8, 2020 7:09 PM
To: Caliguiri, Laura (Laura.Caliguiri@fda.hhs.gov); Hinton, Denise (Denise.Hinton@fda.hhs.gov); Hebert, Angelique A. (Angelique.Hebert@fda.hhs.gov); Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov)
Subject: RE: HHS Call

Here you go! Thank you. Would you let know it has already been sent to ASPA.
Just heard from Catherine Bird. No need to resend my message. They are working to clear it. It might be as early as tonight.

From: "Caliguiri, Laura" <Laura.Caliguiri@fda.hhs.gov>
Sent: Sunday, March 8, 2020 6:19 PM
To: "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>, "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>, "Hebert, Angelique A." <Angelique.Hebert@fda.hhs.gov>, "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

(b)(5)

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Sunday, March 8, 2020 6:12 PM
To: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: HHS Call

Thanks for your update Jim. FWIW, I agree with the approach written in the last two sentences of the third bullet.

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Sunday, March 8, 2020 5:49 PM
To: Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: HHS Call

On a 5:00 HHS call that ASA pulled together. Will Brady joined as well –

A few topics were discussed –

- Clearing our all-hands messages through HHS – Blair Duncan is our POC and we can copy ASPA at the same time

- FAQs – They would like to try to have a single point of entry for questions from staff. We discussed how we have already been receiving questions as have other Opdivs. Not sure what they are going to be able to pull together quickly as a point of entry but we were asked to send our questions and draft answers to Blair to serve as a resource for them,

- We need to tee up our decisions on travel for ASA and ASPA. I don’t think this will be an issue. CDC explained what they are looking to do starting this week in cancelling all non-mission critical travel both domestic and foreign. I do
Please see the attached document for today's call.
Good afternoon TF members,

As a reminder, if you have not sent us your primary two department/agency contacts for supply chain task force work please do so by 2pm today to cip@hhs.gov. We will be working with these contacts to ensure regular touch bases and reporting on activities.

As mentioned, we will be using max.gov as our sharing platform for the task force. If you already have a max.gov account, you have been added to the TF max page. If you do not have a max account, please follow the instructions below and email Luis.Deleon@hhs.gov once you create an account.

Today’s call will be extended by 30 minutes to accommodate for a briefing by Premier Inc on supply chain challenges and global supply chain climate.

Below is the agenda
• 1-1:10 Task Force Overall Update, Processes & Info Sharing
• 1:15-1:45 Premiere Update
• 1:45- 2:10 RPDs
  o COA 1 Updates & Path Forward
  o COA 2 Updates & Path Forward
  o COA 3 Updates & Path Forward
  o COA 4 Updates & Path Forward
• 2:10-2:20 Line of Effort 2
  o Updates & Path Forward
• 2:20-2:30 Global Supply Chain
  o Updates & Path Forward

We look forward to speaking with you then. As a reminder, please login to the webex during the meeting.

How to Register for a MAX.gov Account and
Accessing the HHS Interagency COVID-19 Supply Chain Task Force MAX webpage

(b)(6)
From: Thomas, Audrey A [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=0E1250E3B21344CE89B0D51FF8BAES3A-THOMASA]

Sent: 3/9/2020 3:50:47 PM

To: Wilson, Carolyn [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a78919ec52b7440e94f5928758847404-wilsonc]; Barratt, Ruth [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=a7a14bd5dcd4121849b18beffcebbdb-BARRATTR]; Mendrick, Donna [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=a4a2be78d4cfe4c8fa2685b38cbbd6e25-DMendrick]; Kwan, Jonathan [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=8c10cdb276014cd4de0b399f86ba64ff-Jonathan.Kw]; Braunstein, Emily [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=dd4eb429ab54b56ae58a84dlc0077ba-BraunsteinE]; Nugent, Bridget [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=304aba05001b40518bc37dce94044ff8-Bridget.Nug]; Ruiz, Juan [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=b773dc886cc0d4dfba2ee6919f5cc80e5-Juan.Ruiz]; Johanson, Elaine [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=636a76a574ab4ad4498438b47493217b-Elaine.Johanson]; Patterson, Tucker [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=3ae4eb6c7b20f4c99b8691c7907864d7d-Tpatterson]; Bright, Roselie A. [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=4eef60c88912461ca085bc8763db45c-RXB]; Patel, Keyur [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=70077d1043dc4a8bb0ef774865de60f-Keyur.Patel]; Schneider, Julie [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=9b938530b11846a29dca7d031cdef3d4-Julie.Schneider]; Vasisht, Kaveeta [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=829ef4o2d6284ab4a06db92ebada1dd-VASISHT]; Lee, Christine [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=46b2c861a86482589389ae844485888-LEECHRI]; Welch, Alice [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=82df5457db94aa2a2c6f51ca5a08b1-Alice.Welch]; Araojo, Richardae [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=0474cf3e9aee432980ca8f3b4ad2c1-Araojo]; Hinton, Denise [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97cb4aabb-HINTOND]; Mair, Michael [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7ead7c7961467ab-Michael.Maj]; Finnen, April [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finnen]; Margerrison, Edward [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=12386ce444f645b6f7215d42b265d70-Edward.Marg]; Saha, Anindita [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=3f66595d5a8a4c6f8ffdddbcc7d312-AXS]; Blumkemelor, Donna [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=7676a976c93642f985adabb1f7ef2db8-Donna.Blumk]; Zinn, Rebekah [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=28f2489f571f117971b764ce05a43a8-Rebekah.Zin]; Chada, Kinnera [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=c6477a3fe02e40d7a6d7db540f92ba5-ChadaK]; Smith, Tara [O=CDRH/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=f75e433d7e564d7e848c52843921326-TaraSmith]; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica [jessica.ritchie@yale.edu]; Ciaccio, Laura [laura.ciaccio@yale.edu]

Subject: RE: COVID19

Attachments: Yale University CERSI - COVID-19 Related Sources 030920.docx

Yale University CERSI - COVID-19 Related Sources 030920.docx

FDA-OSJI-FOIA-2020-3541_00006035
FYI. Please find attached a one-pager from Yale University CERSI on Yale’s resources related to COVID-19. If you would like to connect with the Yale University, please contact Joe Ross at joseph.ross@yale.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A  
Sent: Sunday, March 08, 2020 7:03 PM  
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Russ B Altman <Russ.Altman@stanford.edu>; 'Giacomini, Kathy' (Kathy.Giacomini@ucsf.edu) <Kathy.Giacomini@ucsf.edu>; 'Lin, Lawrence' (Lawrence.Lin@ucsf.edu) <Lawrence.Lin@ucsf.edu>; Friciello, Maria (Maria.Friciello@ucsf.edu) <Maria.Friciello@ucsf.edu>
Subject: RE: COVID19

FYI. Russ Altman reached out to me to say that Stanford is in the middle of a crisis. They have a faculty member at the Med School that has tested positive for coronavirus. The school is moving to online classes along with other restrictions. I told Russ not to worry about my request.

I think that this will become more and more prevalent: (b)(6)

Audrey

From: Thomas, Audrey A  
Sent: Sunday, March 08, 2020 11:59 AM  
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; William Bentley <bentley@umd.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>
Subject: RE: COVID19

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I think that this will become more and more prevalent: (b)(6)
As requested, I have reached out to the CERSls for information on their resources related to COVID-19. I just received a one-pager from the University of Maryland CERSI, Baltimore Campus. If you would like to connect with the University of Maryland, please contact James Polli at jpolli@rx.umd.edu (copied on this email).

Thanks.

Audrey Thomas

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>
Sent: Sunday, March 08, 2020 9:17 AM
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patil, Keyur <Keyur.Patil@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Ariaojo, Richardae <Richardae.Ariaojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Subject: RE: COVID19

Many thanks Audrey.

I shared with our CoV coordinator in CBER and we both think it would be great if you could reach out to each of the CERSIs with a similar request. Can’t hurt to be more aware of all potentials out there.

Also, I’m assuming you are sharing the information with OCET as well.

Carolyn

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>
Sent: Sunday, March 8, 2020 7:25 AM
To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patil, Keyur <Keyur.Patil@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Ariaojo, Richardae <Richardae.Ariaojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Subject: FW: COVID19
Importance: High
FYI. As per discussion at Thursday’s Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU’s resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.
Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader
UCSF-Stanford CERSI Program Official (PO)
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 1, Rm 4220
Silver Spring, MD 20903
301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>
Sent: Saturday, March 07, 2020 8:46 PM
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>
Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: COVID19
Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins’ resources that may be relevant to FDA’s COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc’d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH’s Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA’s response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu
Hi Denise,

I’m sorry, I’m still a little unclear about the TP ask for today. I’ve attached the most recent draft TPs from FDA (dated 3/3/20; not yet finalized), but I’m guessing that’s probably not what’s needed. I heard there might be a more updated document (e.g., reactive TPs or something like that) from the weekend? Again, my apologies.

Also, FDA participates in the following regular supply chain meetings/groups (plus a number of ad hoc meetings on various supply chain topics):

- FDA (internal) Supply Chain Work Group (weekly; all Centers and relevant Offices)
- HHS(OS) Supply Chain Task Force (weekly)
- NSC Supply Chain Coordination Work Group (usually 2 times/week, plus subgroup meetings as needed)
- NAPAPI (as needed; meetings usually have some focus on supply chain)

Thanks,
Brooke

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From: Courtney, Brooke
Sent: Monday, March 09, 2020 1:43 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

I can list each supply chain meeting being held that I’m aware of (it seems there are some I’m not aware of that OC is coordinating or participating in) and who’s engaged (to the extent that I know, with the caveat that it might not be complete since, again, I’m not looped into all FDA activities on supply chain.

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From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 09, 2020 1:12 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

Keagan was talking about the OS Supply Chain Taskforce Meeting that Stacy and Janet are attending. He will be going to the WHTF meeting this evening and could use updates for that, if any. It will be helpful to list out each supply chain meeting being held and who’s engaged. You, Michael and I need to know what they are, who’s covering, and what TPs are being used. Anything else?

---

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 9, 2020 1:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting
Thanks, I’m not sure I can get effective TPs together without knowing what the meeting is, and it seems there are other supply chain efforts going on within OC. Thanks.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Sent: Monday, March 09, 2020 12:35 PM  
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

Will seek info from Keagan – it was mentioned walking from one meeting to another today.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
Sent: Monday, March 9, 2020 12:34 PM  
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Subject: RE: Agenda in body of meeting: Supply Chain Taskforce Meeting

Hi Denise,

What is the “1:30 SC”? Also, I’m not aware of some of what’s been going on with the NSC group and am concerned I don’t have the most up to date information that he might need, but I’ll see what I can pull together at 1:00 (I’m leading the internal supply chain WG call now, so I won’t be able to send you any TPs until about 1:15 or so).

Thanks,
Brooke

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Sent: Monday, March 09, 2020 12:28 PM  
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>  
Subject: Agenda in body of meeting: Supply Chain Taskforce Meeting

Please provide most current TPs for Dr. Hahn to reference and to speak to as needed in today’s 1:30 SC and evening WHTF meeting.

Thanks,

Denise

From: OS CIP (HHS/OS) <CIP@hhs.gov>  
Sent: Monday, March 9, 2020 11:08 AM  
Subject: Supply Chain Taskforce Meeting

Good afternoon TF members,

As a reminder, if you have not sent us your primary two department-agency contacts for supply chain task force work please do so by 2pm today to cip@hhs.gov. We will be working with these contacts to ensure regular touch bases and reporting on activities.

As mentioned, we will be using max.gov as our sharing platform for the task force. If you already have a max.gov account, you have been added to the TF max page. If you do not have a max.gov account, please follow the instructions below and email Luis.Deleon@hhs.gov once you create an account.

Today’s call will be extended by 30 minutes to accommodate for a briefing by Premier Inc on supply chain challenges and global supply chain climate.
Below is the agenda

- 1-1:10 Task Force Overall Update, Processes & Info Sharing
- 1:15-1:45 Premiere Update
- 1:45-2:10 RPDs
  - COA 1 Updates & Path Forward
  - COA 2 Updates & Path Forward
  - COA 3 Updates & Path Forward
  - COA 4 Updates & Path Forward
- 2:10-2:20 Line of Effort 2
  - Updates & Path Forward
- 2:20-2:30 Global Supply Chain
  - Updates & Path Forward

We look forward to speaking with you then. As a reminder, please login to the webex during the meeting.

How to Register for a MAX.gov Account and
Accessing the HHS Interagency COVID-19 Supply Chain Task Force MAX webpage

(b)(6)
Good afternoon everyone,

Here is today’s COVID-19 daily guidance update. As always, if you see something that needs to be changed or want to add something, please do not hesitate to contact myself or CAPT Perdue.

This guidance update is being sent out to the HHS PMO list and others by request or need.

Very respectfully,
Will

William Farmer, MS
Presidential Management Fellow - Program Analyst
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements
Division of Requirements

Subject: Daily guidance update
Attachments: 03092020_GuidanceUpdateFinal.pdf
Hello Denise,

Hope you had a nice weekend. I know things must be super crazy right now. Just following up to see if you would have time connect on the COVID-19 and potential application of the Organs-on-Chips technology. We have some new developments that would be great to share with you and to explore how we can involve your team.

Best,
Geraldine.

On Feb 27, 2020, at 11:28 PM, Geraldine Hamilton <Geraldine.Hamilton@emulatebio.com> wrote:

Hello Denise,

Thanks so much for your prompt reply I know you must be super busy.

Tomorrow I am in the office in internal meetings most of the day so it is easy for me to step out and take your call. Please feel free to call my cell any time.

Looking forward to connecting.
Best,
Geraldine.
It’s great to hear from you. I am well and hope you are too. I am not available to meet today due to previously scheduled meetings; however, I am open to having discussions about the Emulate platform r/t COVID-19. I have your number below and will reach out to you at my earliest convenience to discuss. Let me know where you may have an opening today or tomorrow for a brief conversation and I’ll try to make it work.

Thank you,

Denise

From: Geraldine Hamilton <geraldine.hamilton@emulatebio.com>
Sent: Wednesday, February 26, 2020 5:01 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Fitzpatrick, Suzanne <Suzanne.Fitzpatrick@fda.hhs.gov>; Sebastian Hernandez <sebastian.hernandez@emulatebio.com>
Subject: Emulate | Organs-on-Chips | and COVID19
Importance: High

Hello Denise,

Hope all is well with you. I wanted to reach out to you regarding the COVID-19 virus and the potential for the Emulate Organs-on-Chip technology to be applied to answer key questions related to the emerging novel coronavirus outbreak.

We have been communicating with our key contacts (b)(4) Based on their feedback and the questions being raised about the virus. We came up with 3 main ideas on how the Emulate platform could potentially be useful for the ongoing outbreak in two main ways:

3. Efficacy and safety testing of potential antiviral therapeutic candidates

Here are links to some of our publications demonstrating the potential to use Organs-on-Chips for infectious disease:

https://www.biorxiv.org/search/lung%2Bchip

https://www.biorxiv.org/content/10.1101/2020.02.03.931170v1


We are currently putting together a one-page document to capture this (b)(4)

Do you think the FDA would like to be involved in this effort in some way? Would be great to discuss further and get your insights.
This may be very short notice but I plan to be in DC on Thursday - we could explore meeting in person if schedule aligns but totally understand that you must be super busy right now.

Look forward to hearing from you.

Best wishes,
Geraldine.

Geraldine A. Hamilton, PhD
President and Chief Scientific Officer

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Hi CDRH, I know there have been a lot of emails today so I have done my best to compile the requests and divided by outstanding and completed (because it's important to note what you accomplished!). Please feel free to loop in those I missed. I am aware you are working on Cuomo info and I believe [b](5)[/b]...

To Do list of outstanding items Monday

Commissioner Call with Gov. Cuomo re concerns:
- Your approval of the EUA amendment to allow us to add any hospital approved by us to do testing. [b](5)[/b] and
- We need more nasopharyngeal (NP) and oropharyngeal (OP) and viral transport media (VTM) as our stockpile is getting depleted by the Westchester sampling. Manufacturers are saying these are on backorder until May. (aware you are working on this)
- CDRH update on Wadsworth center’s platform
- Status of NY EUA?

Expansion [b](b)(5)[/b]
Ta-Da List (all of the things accomplished)

Change in swabs/Sample Collection

- FDA supports CDC’s move to a single swab for testing, anticipating this change will allow more patients to be tested more quickly without posing any regulatory or supply chain difficulties.

- ACTION/ Follow Up We are finding out from large commercial labs if they have enough supplies for tests and also where they are with swabs to examine if there any critical vulnerabilities that will inhibit their fast ramp up. The team is contact the manufacturers of the swabs and find out about their ability to ramp up supply. [b](5)

Q: Will the change to a single swab for testing require a new EUA or a supplement to the current EUA? Does it work like a regular application that got cleared/approved and then had a change? The commissioner asked for clarity on regulatory steps. …Same question regarding the use of sputum test...
A: For the use of a single sample, as opposed to using multiple samples, no new EUA or EUA amendment would be necessary.

For use of a nasopharyngeal (NP) swab, an oropharyngeal (OP) swab, or sputum, no new EUA or EUA amendment would be necessary for any currently issued EUAs because the claims made by these organizations in their original EUA submission explicitly included analysis of “upper and lower respiratory specimens,” which includes NP or OP swabs and sputum as well as lower respiratory tract aspirates, bronchoalveolar lavage, and nasopharyngeal wash/aspirate or nasal aspirate.

If new EUAs are issued to organizations making more limited claims, e.g. only claiming analysis of “upper respiratory specimens,” and one wanted to use a lower respiratory specimen such as sputum, then an EUA amendment would normally be necessary, e.g. to add lower respiratory specimens to the test claims.

- Beginning assessment ASAP (today without delay) regarding status of the materials that are needed to perform sample collection for COVID diagnostics testing.

- The below excerpt was received from State of New York a short while ago:

- We need more nasopharyngeal (NP) and oropharyngeal (OP) and viral transport media (VTM) as our stockpile is getting depleted by the Westchester sampling.

- Matthew was tasked earlier today to assess the swab situation and now we have an escalating situation beyond swabs to include the transport medium in which the sample is carried.

- Action Items
  1. Suzanne S requested 2 staff members from DARSS to help with this immediately to determine commercial labs supply of swabs, any vulnerabilities in the that will inhibit their first ramp up? Finding out ramp up supply. [b](5) If you can identify right away who those are….I will provide separate guidance but basically we will follow our procedures for assessing product availability.

  2. Hahn Call with Gov Cuomo

WHO TESTS

- There has been some confusion about whether the World Health Organization developed and distributed a diagnostic test. WHO has not developed an in house test, however, they did support distribution of a test that was developed in Germany. They have facilitated the distribution of hundreds of thousands of
these tests worldwide to more than 100 countries, mostly low- and middle-income countries that did not have their own testing protocols.

- WHO selected this test in mid-January test because (1) it was manufactured according to international standards, (2) it was manufactured using the first validated published protocol for testing, and (3) because they knew about the manufacturing and distribution capabilities of the company producing the test.
- This test was distributed after self-validation of its accuracy. However, in the U.S. we require more validation before such wide spread use.
- CDC, which is a World Health Organization Essential Reference Laboratory also created a test like several other countries were doing. Until issues with the test were detected, which were rapidly resolved, there were no reasons to rely on another country’s self-validated test.
- From an earlier exchange with (b)(4)

(b)(5)

Contact for States
- (FL SG) Matthew Diamond
Would it be helpful for these to come to IMG/JIC?

+ Denise

Denise – can you connect with Lindsay on this? Do you think there is value in the IMG getting this info, or if it should still go right to the Centers?

I think it would be helpful if we were answering the kinds of questions the public want to know that is in our FDA lane, and this gives us some good perspectives of what people want to know.

Keagan – we get a ton of emails to the public box on COVID every day. I’ve started having OES send me the emails below but I’m now wondering if these should be sent to the working group? OES still farms assignments out per normal process but I’m wondering if Denise et al should have a chance to see what’s coming in earlier than later. OK for me to have OES send to WG?

Hello Lindsay,

Sorry for the delay.

Wanda
The following letters came in to the Commissioner’s public mailbox.

- The attached documents “Beth Tignor Vanda COVID-19 Treatment Guidelines and Fellow Orthodox Christian” shares the guidelines which was prepared by Dr. Michael Polmeropoulos, one of the leading minds in the pharmaceutical industry. He notes that the medication “Chloroquine” has been treating the majority of the coronavirus patients has been used in America since 1949. (OES will log in and share with CDER as FYI.)

- The attached document “One Step COVID-19 test kits” shares information regarding one of the China sourcing and supplier for the One step COVID-19 test kits that he deals with to assist FDA in the addressing the shortage of test kits to detect the coronavirus. (OES will log in and assign to CDRH as a D/R.)

- The attached document “Monte Bay Drug Stores” submits recommendations to FDA on how to contain and prevent the spread of the coronavirus. (OES will log in and to Denise Hinton as FYI.)

- The attached document “Rajamanna Coronavirus” physician suggests to FDA that he feels it would be helpful to have a tracking system for known exposures to the coronavirus. (OES will log in to Denise Hinton as FYI.)

- The attached document “Robert Ford Quick Follow-up” to Dr. Hahn from Robert Ford, Abbott Laboratories letting him know the Abbott is committee to assisting in brings diagnostic tests for the coronavirus to the American people. He provides Dr. Hahn an update. (OES will log in to CDRH as FYI.)

- The attached 3 documents “Roman Terrill 2 and 3, plus Roman Terrill Coronavirus Testing Capacity” to Dr. Hahn and others including CDC from Roman Terrill, Senior Vice President, IDT regarding coronavirus testing capacity. (OES will log and share with CDRH as FYI.)

- The attached document “Coronavirus-Testing Capacity” from Timothy Stenzel, MD (CDRH) in response to Raul Perea-Henze, MD, MPH, Deputy Mayor for Health & Human Services, City of New York regarding the coronavirus testing capacity. (OES will log in for the record.)

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Denise

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 10:18 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: FW: Coronavirus Documents for March 9th

Importance: High

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To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Cc: O’Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
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From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/10/2020 11:21:44 AM
To: Mair, Michael [Michael.Mair@fda.hhs.gov]; Mignone, Alfred [Alfred.Mignone@fda.hhs.gov]; Finnen, April [April.Finnen@fda.hhs.gov]
Subject: FYSA: Coronavirus Documents for March 9th

From: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:21 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

Great, thanks!

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:15 AM
To: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

Thanks for asking Lindsay. It can go the Centers; however, it would be helpful to send to the IMG AICs (Michael Mair and Alfred Mignone)/JIC (April Finnen) for awareness. Especially, if there is any action/response requested from any of the Centers/ora.

Thank you,

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Sent: Tuesday, March 10, 2020 11:03 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Coronavirus Documents for March 9th

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From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
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From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 11:27 AM
To: Tse, Tania <Tania.Tse@fda.hhs.gov>; Branch, Tiffany <Tiffany.Branch@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Subject: FYSA: + slides - RE: Notes for 9:30 JIC meeting

Thanks!

From: Finnen, April <April.Finnen@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 10:28 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: + slides - RE: Notes for 9:30 JIC meeting

New: Slides for today’s 1:30 meeting. RE: streamlining the JIC process (send any thoughts before then, please)

Meeting notes are posted for reference. Thanks everyone for your continued help and support!

From: Finnen, April
Sent: Tuesday, March 10, 2020 7:43 AM
To: 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Notes for 9:30 JIC meeting

Good morning, JIC team.

After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

NOTE: Send all COVID-19-related OCC clearance requests to this mailbox, starting now:
OCCRequests-COVID19@fda.hhs.gov

30 minutes, WebEx/call only today. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

We’ll cover:
• Cleared language to use publicly around canceled meetings; multiple centers/offices – Heidi to draft/clear w/OO 3/9 – update?
• Info for daily WH press briefing – what #s, etc. do we need today? Tweeting #s daily? (Stephanie)
• New writing assignment (or copy/paste cleared info): QA responses for Dr. Shah – add your center/office responses to this draft by noon Thursday 3/12 (CDER, CBER, ORA, CVM, CFSAN, OCC, OCET)
• At this step we are drafting. Once input added, will route for JIC/IMG review.
- Will fold into cleared weekly TPs once finalized and cleared through OCC.
- Meeting report-out (all who covered meetings yesterday)
- Media monitoring (Anne)
- Status checks (see Reviews table below)
- Proactive: what’s new / coming soon?

### Reviews:

<table>
<thead>
<tr>
<th>Comm</th>
<th>Clearance Due</th>
<th>Contact (JIC)</th>
<th>Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Senate HELP Letter on FDA Inspection Personnel</td>
<td>March 5 COB overdue</td>
<td>Caitlin Pennington / Matthew Lockheed</td>
<td>Waiting on statement to go (likely Tuesday morning)</td>
<td>Specifically need a response to Q4: How is FDA communicating information and/or policies related to inspections in China to its workers and/or union representatives? ...</td>
</tr>
<tr>
<td>Letter from Representatives Schakowsky, Doggett and DeLauro regarding COVID-19 testing capacity</td>
<td>March 10, 10:00 a.m.</td>
<td>Taylor Price</td>
<td>JIC/IMG</td>
<td>In advance of the Commissioner’s FY21 House Budget hearing on March 11, OCA is seeking to collect talking points for the Commissioner’s use. Optional (need CDRH input)</td>
</tr>
<tr>
<td>MCMi stakeholder email</td>
<td>March 10, 11:00 a.m.</td>
<td>April Finnen</td>
<td>JIC/IMG</td>
<td></td>
</tr>
<tr>
<td>Coronavirus Health Fraud Products (Pre-recorded interview) Spanish (see email attachment ➔)</td>
<td>March 10, 11:00 a.m.</td>
<td>Gloria Sanchez-Contreras</td>
<td>JIC/IMG</td>
<td>Coronavirus Health Fraud Products (Pre-recalled talk at the annual meeting of America’s Blood Centers (ABC) on 3/10) Draft response for Dr. Hahn to consumer inquiry. Please use plain language.</td>
</tr>
<tr>
<td>Blood supply remarks Dr. Marks (comments on blood donation)</td>
<td>March 10, 11:00 a.m.</td>
<td>Lorrie McNeill</td>
<td>JIC/IMG</td>
<td></td>
</tr>
<tr>
<td>Consumer response letter</td>
<td>March 10, 2:00 p.m.</td>
<td>April Finnen</td>
<td>JIC/IMG</td>
<td></td>
</tr>
<tr>
<td>Letter from Sens. Warren &amp; Casey on fraudulent products</td>
<td>March 10, COB</td>
<td>Caitlin Pennington / Matthew Lockheed</td>
<td>JIC/IMG</td>
<td></td>
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<tr>
<td>Sen. Reed letter (OCA)</td>
<td>March 10, COB</td>
<td>Taylor Price</td>
<td>JIC/IMG</td>
<td>On preparedness</td>
</tr>
<tr>
<td>Sen. Murray letter on COVID-19 Testing</td>
<td>March 12, COB</td>
<td>Caitlin Pennington / Matthew Lockheed</td>
<td>JIC/IMG</td>
<td></td>
</tr>
<tr>
<td>Op-ed on fraudulent products (link may be outdated version)</td>
<td>TBD</td>
<td>Laura Caliguri</td>
<td>ASPA</td>
<td>Cleared by Dr. Hahn March 4; stuck at HHS</td>
</tr>
<tr>
<td>FDA Voices on PHS all hands/response support</td>
<td>TBD</td>
<td>Brooke Leggin</td>
<td>Commissioner</td>
<td>Put in Commissioner’s homework March 4 &amp; 6 (next goes to ASPA?)</td>
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<tr>
<td><strong>Website FAQs</strong> (fda.gov)</td>
<td>March 9, 9:00 a.m. overdue</td>
<td>Brooke Leggin</td>
<td>OCC (final step before we post) OGC/GLD (clearing OO/HR Q&amp;As, at OCC request)</td>
<td>Targeting to publish March 9 (does not AEG review – taken from previously cleared info) JIC reviews completed March 6; with Tania Tse for GLD clearance</td>
</tr>
<tr>
<td><strong>Inside FDA FAQs for employees</strong></td>
<td>March 5 overdue</td>
<td>Tina Harrison</td>
<td></td>
<td></td>
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<tr>
<td><strong>APhA Coronavirus Emergency Responders</strong></td>
<td>March 4 overdue</td>
<td>Lori MacLennan / Lena Choe</td>
<td>Moved to HHS/ASPA at 2:00 p.m., 3/9; clearance requested by COB 3/11</td>
<td>Short article intended for publishing in the <em>Journal of the American Pharmacists Association</em>; highly supported (+ cleared) by CDER leadership to highlight the response work of CDER’s PHS officers</td>
</tr>
<tr>
<td><strong>COO all hands message on travel policy</strong></td>
<td>TBD</td>
<td>Sandy Walsh w/OO</td>
<td>Complete</td>
<td>JIC has not seen a draft; Update: message sent 3/9 – JIC not asked to review/clear (unclear what process this followed)</td>
</tr>
<tr>
<td><strong>FDA statement on inspections</strong></td>
<td>March 9</td>
<td>Heidi Rebello / Stephanie Caccamo</td>
<td>ASPA/WH</td>
<td>JIC/IMG and OCC cleared 3/9 (target 3/10 to issue)</td>
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<tr>
<td><strong>Rep. Meng + 13 on COVID-19 testing</strong></td>
<td>March 13, COB</td>
<td>Caitlin Pennington / Matthew Lockheed</td>
<td>JIC/IMG</td>
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<tr>
<td><strong>Rep. Schakowsky, Doggett, &amp; DeLauro letter on COVID-19 testing affordability</strong></td>
<td>March 16, COB</td>
<td>Caitlin Pennington / Matthew Lockheed</td>
<td>JIC/IMG</td>
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<tr>
<td><strong>Rep. Crist letter on Coronavirus diagnostic availability</strong></td>
<td>March 16, COB</td>
<td>Caitlin Pennington / Matthew Lockheed</td>
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<td>** Anything else currently in clearance?**</td>
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### FUTURE COMMS

<table>
<thead>
<tr>
<th>Daily tweets</th>
<th>Daily before 3:00 p.m.</th>
<th>Abby Capobianco</th>
<th>Ongoing: time-sensitive Commissioner tweets need to be AEG-cleared before 3:00 p.m. daily</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weekend / evergreen tweets</td>
<td>Friday before 3:00 p.m. Several overdue</td>
<td>Abby Capobianco</td>
<td>AEG Ongoing: need any Commissioner tweets for weekend AEG-cleared before 3:00 p.m. Fridays</td>
</tr>
<tr>
<td>Comm</td>
<td>Clearance Due</td>
<td>Contact (JIC)</td>
<td>Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)</td>
</tr>
<tr>
<td>------</td>
<td>---------------</td>
<td>---------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>Weekly talking points</td>
<td>Weekly, Wednesdays at noon</td>
<td>Siobhan DeLancey</td>
<td>Drafting</td>
</tr>
<tr>
<td>Statement on FDA response activities, to provide update on areas including diagnostics, inspections, and supply chain</td>
<td>TBD</td>
<td>Stephanie Caccomo</td>
<td></td>
</tr>
</tbody>
</table>

Reminders/notes/discussion:
- **Reminders:**
  - ACTION: Send Caitlin Pennington an email with your info for the JIC Contact list
  - SharePoint works best in Internet Explorer (if IE is not your default browser, copy/paste the SP links from emails)
  - No spaces in filename
  - Use the format YYYYMMDD_Filename
- **Things to bookmark:**
  - Main IMG SharePoint folder (review SITREPS daily, late afternoon)
  - Main JIC folder – includes clearance process checklist w/clearance legend
- **In progress:**
  - Talking points vs. WH Task Force daily TPs vs. cleared media responses
    - Updating TPs daily – this will be urgent task every day; will have updated talkers of the hot topic(s) of the day; OMA (Stephanie) will compile as a master list
- Meeting report out / coverage (see Op Tempo for dial-in #s)
  - Standing meetings updates (task forces, etc.)
  - Hearings/Hill briefings
  - White House press conference/TF
  - 3/9 AEG discussion (Laura, Heidi, April) – FAQs Dr. Shah wants answers to questions below – JIC drafting responses:
    - Impact on critical medicines primarily made in the U.S.? (CDER / CBER / OCE)
    - Impact of wholesale disruptions to domestic inspections? (ORA)
    - Will I still be able to find pet food at my local store? (CVM)
    - Approach to unsafe food products or foodborne illness outbreaks? (CFSAN)
    - Are there additional opportunities for regulatory relief during the outbreak? (OCC)
- Media monitoring report out (Anne) – notes on SharePoint
- ...
Denise and Michael,

As a heads up, the NSC Supply Chain Coordination WG has drafted a paper on ventilators. FDA and CDC already provided significant comments and edits, and the group met yesterday to discuss them. If you have any comments/edits on the attached, just let me know by 4:00 pm tomorrow (3/11)—CDRH already has this for review. We’ve been asked to return it to the NSC by tomorrow afternoon.

Thanks,
Brooke

---

All,

Thank you for a productive call yesterday afternoon.

Attached, please find the next round of a draft of the COA paper for ventilators. I tried to incorporate the edits that you sent last week as well as things I captured in my notes yesterday.

Please fact check, add thoughts, edits, etc.

Appreciate your edits by 5pm EDT on March 11.

Thank you in advance.

Please reach out with any questions or concerns.

-Sara

---

Sara K. Mroz
National Security Council, Resilience Directorate
From: Roth, Lauren /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=52BFD08572694F269A20C508F3C04A03-LAUREN.ROTH
Sent: 3/10/2020 3:02:26 PM
To: Lenihan, Keagan /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=ee7320ee88e08184d66bf6521b0105d172-Keagan.Lenien]; Amin, Stacy /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06f6af8-Stacy.Amin]; Anderson, Erika /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=9860692bba64edfb25aba1e3573dfde-eranders]; Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=85feca40e694803be6030e97c7b4ad-hinton]; Mair, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=f451bdad7564d7fac7eadc7961467ab-Michael.Laመ;
CC: Schiller, Lowell /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=77949b06919e4f1aa788e9a616c50c7-Lowell.Schiller]; Cohen, Kenneth /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOBF23SPDLT)/cn=Recipients/cn=44f565b7b39e4879bd316ca2e136bc-Kenneth.Coh
Subject: FW: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]
Importance: High

Keagan, Erika, Stacy, Denise, Michael –

We just received a copy of the attached documents from the department. **Deadline is 3:30 today.** We can quickly review in OP; does anyone else in FDA need to see it?

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From: Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 2:59 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Cc: Helmanis, Lisa M <Lisa.Helmanis@fda.hhs.gov>; Gillum, Jessica Z (FDA) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Rooths, Tarita <Tarita.Rooths@fda.hhs.gov>
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Ken

---

From: Horska, Katerina (HHS/IOS) <Katerina.Horska@hhs.gov>
Sent: Tuesday, March 10, 2020 2:11 PM
To: Bradsher, Kris (OS) <Kris.Bradsher@hhs.gov>; Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@hhs.gov>; Hall, Bill (OS) <bill.hall@hhs.gov>; Pence, Laura (OS) <Laura.Pence@hhs.gov>; Tatem, Anne (OS) <Anne.Tatem@hhs.gov>; Murphy, Ryan (OS) <Ryan.Murphy@hhs.gov>; Robinson, Michael J (OS) <michael.robinson@hhs.gov>; ASPE Exec Sec (OS/ASPE) <ASPEExecSec@hhs.gov>; Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Oakley, Caitlin B (OS) <Caitlin.Oakley@HHS.GOV>; Clark, Cynthia (CDC) <cfc8@cdc.gov>; Hoffmann, Lauren (CDC) <cph5@cdc.gov>; Campbell, Taylor (OS) <Taylor.Campbell@hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; Gillum, Jessica Z (FDA) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Varnado, Martina

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OGC and Paula Stannard have already reviewed the FRN. Please let me know if you have any concerns or edits to any of the documents by NLT 3:30 PM today. We are aiming to sign the package today.

Thank you,

Katerina

Katerina Horska
Policy Coordinator
Immediate Office of the Secretary, Executive Secretariat
U.S. Department of Health & Human Services
Room 629H, Humphrey Building
Office: 202-690-6819
Cell: (b)(6)

From: Horska, Katerina (HHS/IOS)
Sent: Tuesday, March 10, 2020 12:06 PM
To: Bradsher, Kris (HHS/ASL) <Kris.Bradsher@hhs.gov>; Ray Gorrie, Jennifer (HHS/OGC) <Jennifer.Ray-Gorrie@hhs.gov>; Hall, Bill (HHS/ASPA) <bill.hall@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Tatem, Anne (HHS/ASPA) <Anne.Tatem@hhs.gov>; Murphy, Ryan (ASPA) <Ryan.Murphy1@hhs.gov>; Robinson, Michael J (HHS/ASPA) <michael.robinson@hhs.gov>; ASPE Exec Sec (ASPE) <ASPEExecSec@hhs.gov>; Sherman, Susan (HHS/OGC) <Susan.Sherman@HHS.GOV>; Johnston, Darcie (HHS/IEA) <Darcie.Johnston@hhs.gov>; Oakley, Caitlin B. (OS/ASPA) <Caitlin.Oakley@HHS.GOV>; Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Campbell, Taylor (OS/OASH) <Taylor.Campbell@hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>; Gillum, Jessica Z (FDA/FOIA) <Jessica.Gillum@fda.hhs.gov>; Chesemore, Scott <Scott.Chesemore@fda.hhs.gov>; Zebley, Kyle (HHS/OGA) <Kyle.Zebley@hhs.gov>; Varnado, Martina (FDA/OC) <Martina.Varnado@fda.hhs.gov>; Allen-Gifford, Patrice (NIH/OD) <Patrice.allen-gifford@nih.gov>; Barry, Daniel J (HHS/OGC) <daniel.bARRY@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>; Chang, William (HHS/OGC) <William.Chang@hhs.gov>; Clark, Cynthia K. (CDC/OD/OCS) <cfc8@cdc.gov>; Hecht, Jonah (HHS/OGC) <Jonah.Hecht@hhs.gov>; Hittle, Taylor (HHS/ASFR) <Taylor.Hittle@hhs.gov>; Hoffmann, Lauren (CDC/OD/OCS) <cpf5@cdc.gov>; Moughalian, Jen (HHS/ASFR) <Jen.Moughalian@hhs.gov>; Pence, Laura (HHS/ASL) <Laura.Pence@hhs.gov>; Schaeffer, Alison (HHS/ASPA) <Alison.Schaeffer@hhs.gov>; Stannard, Paula (HHS/IOS) <Paula.Stannard@hhs.gov>; Steele, Danielle (HHS/IOS) <Danielle.Steele@hhs.gov>; Stimson, Brian (HHS/OGC) <Brian.Stimson@hhs.gov>
Good morning,

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Thank you,

Katerina

Katerina Horska
Policy Coordinator
Immediate Office of the Secretary, Executive Secretariat
U.S. Department of Health & Human Services
Room 629H, Humphrey Building
Phone: 202-690-6819
From: Hinton, Denise (/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/10/2020 3:15:53 PM
To: Sadove, Elizabeth [Elizabeth.Sadove@fda.hhs.gov]
Subject: FW: For your review by 3:30 PM Today: PREP Act Declaration Today [COVID-19]
Importance: High

Adding Liz

From: Roth, Lauren <Lauren.Roth@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 3:02 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; Cohen, Kenneth <Kenneth.Cohen@fda.hhs.gov>
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Cell: (b) __ __ __ __

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Katerina

Katerina Horska
Policy Coordinator
Immediate Office of the Secretary, Executive Secretariat
U.S. Department of Health & Human Services
Room 629H, Humphrey Building
Phone: 202-690-6819
Hi Lauren,

OCS/OCET reviewed and clears with no comments or proposed revisions. Liz specifically reviewed the relevant section re: “covered countermeasures” and that reads as we had previously recommended.

Thanks,

Denise

Keagan, Erika, Stacy, Denise, Michael –

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Cc: Agnew, Ann (HHS/IOS) <Ann.Agnew@hhs.gov>; Robinson, Wilma (HHS/IOS) <Wilma.Robinson@hhs.gov>; ASPR Exec Sec (OS/ASPR) <ASPRExecSec@hhs.gov>; Shuy, Bryan (OS/ASPR/IO) <Bryan.Shuy@hhs.gov>; Bratcher-Bowman, Nikki (OS/ASPR/IO) <nikki.bratcherbowman@hhs.gov>; Hawkins, Jamar (HHS/OS) <jamar.hawkins@hhs.gov>; Malliou, Ekaterini (OS/IOS) <Ekaterini.Malliou@hhs.gov>; Dareshori, Zack (HHS/IOS) <Zachary.Dareshori@hhs.gov>; Bird, Catherine (OS/OGC) <Catherine.Bird@hhs.gov>
Subject: Forthcoming PREP Act Declaration Today [COVID-19]

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Thank you,

Katerina

Katerina Horska
Policy Coordinator
Immediate Office of the Secretary, Executive Secretariat
U.S. Department of Health & Human Services
Room 629H, Humphrey Building
Good afternoon,

The attached has been submitted to OO for review. It still needs a technical editor polish it up, as we ran out of time to have that undertaken here. We were able to capture the additions and addressed most if not all of the questions/comments (last set received at 14:13 today). Please let me know if you have any questions and/or concerns.

v/r

Tom

CAPT Thomas Mignone
Deputy Agency Incident Coordinator
2019 Novel Coronavirus (nCoV) IMG
U.S. Food and Drug Administration
Desk 301-796-7635
Cell: (b)(6)
Email: alfred.mignone@fda.hhs.gov

From: Carter, Lionel <Lionel.Carter@fda.hhs.gov>
Sent: Tuesday, March 10, 2020 4:34 PM
To: Sigg, Jim <Jim.Sigg@fda.hhs.gov>; Hebert, Angelique A. <Angelique.Hebert@fda.hhs.gov>
Cc: Yancey, Carolyn A (OCIO) <Carolyn.Yancey@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Subject: FDA COVID19 CONOP Plan

Jim

Here is the CONOP Plan for COVID19. I believe we have captured all the comments/edits that were provided to us by 10 pm on Monday, March 9, 2020. However, I believe Monica Ellerbe is currently working on updates for OFBA. We can discuss how to incorporate any comments they may have after your review. I just did not want to hold this up any longer.

V/r

Lionel Carter Acting Director
Office of Security and Emergency Management
10903 New Hampshire Avenue, WO32- RM1353
Silver Spring, MD 20993
PH:301-796-2796 | Mobile: (b)(6)
Lionel.Carter@fda.hhs.gov
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOBF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/10/2020 5:32:25 PM
Subject: For REVIEW: COVID-19 PMO Materials for March 11, 2020
Attachments: COVID-19 HHS PMO Daily Sync Call Agenda_FINAL.docx; COVID-19 HHS PMO Summary 2020-03-10.docx; COVID-19 PMO Tracker 3-10.docx

From: Mango, Paul (HHS/IOS) <Paul.Mango@hhs.gov>
Sent: Tuesday, March 10, 2020 5:25 PM
To: Pollard, Ashton (OS) <Ashton.Pollard@hhs.gov>; Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; McGowan, Robert K (CDC) <omc2@cdc.gov>; Imbriale, Samuel (OS) <Samuel.Imbriale@hhs.gov>; Mccreary, Kenneth (OS) <Kenneth.Mccreary@hhs.gov>; Perdue, Christopher (OS) <Christopher.Perdue@hhs.gov>; DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>; Phillips, Sally (OS) <Sally.Phillips@hhs.gov>; Pratt, Michael (OS) <Michael.Pratt@hhs.gov>; Renihan, Keagan <Keagan.Renihen@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Johnston, Darcie (OS) <Darcie.Johnston@hhs.gov>; Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Chang, William (OS) <William.Chang@hhs.gov>; Trueman, Laura (OS) <Laura.Trueman@hhs.gov>; Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>; Fernandez, Jose A (OS) <Jose.Fernandez@hhs.gov>; Elvander, Erika (OS) <Erika.Elvander@nih.gov>; Valentine, Steven (OS) <Steven.Valentine@nih.gov>; Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>; Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>; Moudy, Robin (OS) <Robin.Moudy@hhs.gov>; Gregg, William J (CDC) <hie6@cdc.gov>; Patel, Anita (CDC) <bop1@cdc.gov>; Dreyzehner, John J (CDC) <pw3n@cdc.gov>; McNellis, Robert (AHRQ) <Robert.McNellis@ahrq.hhs.gov>; Levine, Cheryl (OS) <Cheryl. Levine@hhs.gov>; Kouzoukas, Demetrios (CMS) <Demetrios.Kouzoukas@cms.hhs.gov>; Kibunja, Julia (OS) <Julia.Kibunja@hhs.gov>; Cochran, Norris (OS) <norris.cochran@hhs.gov>; Dasher, David (OS) <David.Dasher@hhs.gov>; Bettencourt, Alice (OS) <alice.bettencourt@hhs.gov>; Moughalian, Jen C (OS) <jen.moughalian@nih.gov>; Hittle, Taylor (OS) <Taylor.Hittle@hhs.gov>; Brookes, Brady (CMS) <brady.brookes@cms.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Parker, Jim (OS) <jim.parker@hhs.gov>; Agnew, Ann (OS) <Ann.Agnew@hhs.gov>; Steele, Danielle (OS) <danielle.steele@hhs.gov>; Brooks, John (CMS) <John.Brooks@cms.hhs.gov>; Stannard, Paula (OS) <Paula.Stannard@hhs.gov>; Brady, William (OS) <William.Brdy@hhs.gov>; Uehlecke, Nicholas (OS) <Nicholas.Uehlecke@hhs.gov>; Keckler, Charles (OS) <Charles.Keckler@hhs.gov>; Smith, Brad (CMS) <brad.smit@cms.hhs.gov>; Giroir, Brett (OS) <brett.giroir@hhs.gov>; Horska, Katerina (OS) <Katerina.Horska@hhs.gov>; Arbres, Sarah C (OS) <Sarah.Arbres@hhs.gov>; Baker, Michael G (OS) <Michael.Baker@hhs.gov>; Lincoln, Carol (OS) <Carol.Lincoln@hhs.gov>; Newland, Matthew J (OS) <Matthew.Newland@hhs.gov>; Oshansky, Christine (OS) <Christine.Oshansky@hhs.gov>; Destro, Brenda (OS) <Brenda.Destro@hhs.gov>; Nevel, Amy (OS) <Amy.Nevil@HHS.GOV>; Twomey, John K (OS) <John.Twomey@HHS.GOV>; Bradway, Courtney B (OS) <Courtney.Bradway@hhs.gov>; Weakhee, Michael (IHS) <Michael.Weakhee@hhs.gov>; Paden, Maris (OS) <Maris.Paden@hhs.gov>; Shuy, Caitrion (OS) <Caitrion.Shuy@hhs.gov>; Aasen, Adam (OS) <Adam.Aasen@hhs.gov>; Robertson, Lance (ACL) <Lance.Robertson@acl.hhs.gov>; McGuffee, Tyler Ann (OS) <TylerAnn.McGuffee@hhs.gov>
Cc: Aviles, Natalie (OS) <Natalie.Aviles@hhs.gov>; Knutson, Donna B (CDC) <dbk2@cdc.gov>; Austin, Meredith (uscg.mil) <Meredith.L.Austin@uscg.mil>; OS Secretaries Operations Center <hhs.soc@hhs.gov>; SOC Information Management Section Chief (OS/ASPR) <SOC.IM@hhs.gov>; Espinosa, Gregorio (OS) <Gregorio.Espinosa@hhs.gov>; Bermingham, John (CDC) <uvk7@cdc.gov>; Maples, David L (CDC) <idr0@cdc.gov>; Harrison, Brian (OS) <Brian.Harrison@hhs.gov>; Berger,
Subject: COVID-19 PMO Materials for March 11, 2020

PMO Team: Here are the materials for tomorrow’s meeting:

- COVID-19 HHS
- COVID-19 HHS
- COVID-19 PMO
- PMO Daily Sync
- PMO Summary 2
- Tracker 3-10.docx

Also, I am including the final infection control guidance hotlink of the document ASPA cleared near the end of our meeting today

Good afternoon everyone,

Here is today’s COVID-19 daily guidance update. As always, if you see something that needs to be changed or want to add something, please do not hesitate to contact myself or CAPT Perdue.

Note the guidance from CDC about dialysis that was discussed in today’s meeting is included.

This guidance update is being sent out to the HHS PMO list and others by request.

Very respectfully,

Will

William Farmer, MS
Presidential Management Fellow - Program Analyst
Office of the Assistant Secretary for Preparedness and Response
Office of Strategy, Policy, Planning, and Requirements
Division of Requirements
See minor revision for consideration. I agree with Erika’s comments. Does Suzanne Schwartz need to lay eyes on it?

Thanks,

Denise

Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301-348-1856
stephanie.caccomo@fda.hhs.gov
COVID-19 Response update Mar 12, 2020
INTERNAL - NOT FOR FURTHER DISTRIBUTION

(b)(5)
(b)(5)
(b)(5)
(b)(5)
(b)(5)
(b)(5)
(b)(5)
Very Respectfully,

**Secretary’s Operations Center**
U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington D.C. 20201
Office (202) 619-7800
Fax: 800-514-4256
Email: hhs.soc@hhs.gov

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Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

Hi Keagan and Denise,

As described below, the

(b)(5)

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC
Sent: Thursday, March 12, 2020 3:04 PM
To: Eric.Rollison@fda.hhs.gov; Glenn, Robert (b)(6) mark.fleming@fda.hhs.gov; Peck, Travis G MAJ USARMY DLA LOGISTICS OPERATIONS (USA
; LaBrecque, Michael F (Mike) COL USARMY DLA LOGISTICS OPERATIONS (USA
; Glasier, Donna J. b)(6) GlasserJ; O'Brien, Kristina M SES JS J4 (USA
; Brown, Christopher K. - OSHA Zebley, Kyle (OS) <Kyle.Zebley@hhs.gov>; Marston, Hilary D (NIH)
; Glascier, Donna J. b)(6) Glasser; O'Brien, Kristina M SES JS J4 (USA
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; Heathertrew@treasury.gov; Paul.Ahern@treasury.gov; Wolf, Laura K (OS) <Laura.Wolf@hhs.gov>; Adams, Steven A (CDC) <SAA1@CDC.GOV>; Alexis.Haakeness@trade.gov; Bartosh, Ernest (Federal Reserve Board) <EBartosh@board.gov>; Edens, Mandy OSHA <Mandy@OSHA.GOV>; Nazak.Nikakhtar@trade.gov; Patel, Anita (CDC) <BP1@CDC.GOV>; Hanson, Elizabeth A Col USAF JS J4 (USA
; Floren, Robert W. EOP/OSTP; Sinclaire, Michael R. EOP/NSC; Goel, Andrea L. EOP/OMB; Hoelscher, Doug; Fabina, Alice
; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Douglas L. EOP/WHO;; Goel, Andrea L. EOP/OMB; Hoelscher, Doug; Fabina, Alice
; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Douglas L. EOP/WHO;; Goel, Andrea L. EOP/OMB; Hoelscher, Doug;Fabina, Alice
Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) meeting of the SCCWG will be cancelled.

Path forward for the SCCWG

Thanks,
Seth.

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

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Sent: Wednesday, February 26, 2020 3:15 PM
To: Jonas, Seth H. EOP/NSC; Eric.Rollison; Glenn, Robert; mark.fleming; david.wade; Polowczyk, John; P RADM USN JS J4 (USA); O BRIEN, Kristina M SES JS J4 (USA); Kless, David; Ronald SES DLA LOGISTICS OPERATIONS (USA); LaBrecque, Michael F (Mike) COL US ARMY DLA LOGISTICS OPERATIONS (USA); Peck, Travis G MAJ US ARMY DLA LOGISTICS OPERATIONS (USA); thomas.j.browning; william.t.viar; Brown, Christopher K. - OSHA; Glasser; donna.o'berry; S60.Policy@dot.gov; matthew.smith@hhs.gov; Jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov; Kristin.DeBord@hhs.gov; Zebley, Kyle (HHS/OSA/OGA); Marston, Hilary (NIH/NIAID) EF; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal); Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; bop1@cdc.gov; Hanson, Elizabeth A COL USAF JS J4 (USA);
Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecon (202)395-6392

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available
Sent: 3/12/2020 3:32:23 PM
To: Lenihan, Keagan [o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320e8c184d66bfdf521b0105d17d2-Keagan.Len]
Subject: RE: COV-Supply Chain Coordination Working Group

(b)(5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting? (b)(5)

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

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To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

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Path forward for the SCCWG
Thanks,

Seth.

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Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov; amie.kalsbeek@dot.gov; Cavanaugh, Brian J. EOP/NSC; Troye, Olivia EOP/NSC; Benjamin Carlson; Mroz, Sara K. EOP/NSC; Bedan, Morgan E. EOP/WHO; LaBreque, Michael F (Mike) COL US ARMY DLA LOGISTICS OPERATIONS (USA); Dragseth, John; Lerner, Andrea (NIH/NIAID) [E]; KEENE, CHRISTOPHER; Scott, Heather; Zapata, Carmen; Kroese, Daniel; Diana, Kevin; Ahr, Daniel; Sally.phillips@hhs.gov; Rausch, John T CIV OSD OUSD A-S (USA; Wurst, Nathan J CTR OSD OUSD A-S (USA; Copes, Robert B (Brian) Col USAF OSD OUSD A-S (USA; Wilkinson, David; Armstrong, Sue E; S C GRCU Walrod, Margaret H (Beijing); PRUE, ANGELA (CTR); vig8@cdc.gov; Stevens, Kathleen E; Dole, Mark J COL US ARMY LOG HA (USA); Jesse.Baker@treasury.gov; Jennison, Peter J. EOP/NSC; Ashok.Pinto@treasury.gov; Anderson, Jacob; Alexander, Christopher; Brown, Gregory (OST); Abigail.Demopulos@treasury.gov; Sappenfield, Christine A; Powers, Billy; Joseph.Clark2@treasury.gov

Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: EEOB Rm 428 or Telecon (202)395-6392,

COV-Supply Chain Coordination Working Group

Will update and agenda and read aheads become available

FDA-OSJ-FOIA-2020-3541_00006957
Before we ask for you to continue – do you have time on your calendar and do you want to attend/participate in these meetings? Okay with MM?

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Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group

Is this a daily in person meeting? Brooke is the one that understands this and is a part of it. A/S level is stretched thin. Would like to understand why they are elevating.

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Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the NSC Supply Chain Coordination WG is transitioning to become a PCC. By tomorrow (Friday, 03/13/2020) COB, we need to reconfirm who the principal member will be for FDA. Generally, PCCs should be attended at the Assistant Secretary level, so it seems to make sense for one of you to be the new principal. However, I’m happy to help support your efforts on this moving forward and have TS clearance if you were to ever need extra coverage.

Thanks,
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Sent: Thursday, March 12, 2020 3:04 PM
To: Glenn, Robert (b)(6); Polowczyk, John P RADM USN JS J4 (USA) (b)(6); OBRIEN, Kristina (b)(6)

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow’s meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. By
tomorrow (Friday, 03/13/2020) COB, could you please reconfirm who the principal member is for your agency. Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

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Where: EEOB Rm 428 or Telecon

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available.
From: June Wasser

Sent: 3/12/2020 3:44:25 PM

To: Hinton, Denise 

Subject: (FYDI BO HF 23SPDL T)/ cn=Recip ients/ en =85feca0be0694803be6030e97c7b4adb-HINTOND

Re: rtPCR testing Question

Thanks so much!

Sent from my iPhone

On Mar 12, 2020, at 3:42 PM, Hinton, Denise <denise.hinton@fda.hhs.gov> wrote:


Let me know if she runs into a roadblock and I’ll try to make the direct connection.

Note – today the FDA launched a diagnostics specific 24/7 call center starting at 1200 today. It is being manned by PHS officers that are trained up on specifics to what is happening with COVID-19 on the lab and diagnostics front.

Those needing assistance can call 1-888-INFO FDA (463-6332) or email COVID19DX@fda.hhs.gov.

Thanks,

Denise

From: June Wasser

Sent: Thursday, March 12, 2020 1:41 PM

To: Hinton, Denise

Subject: rtPCR testing Question

Hi Denise,

I hope you are well and I suspect very busy so I’ll keep this short. A colleague of mine wants to know (and asked for my help facilitating if possible) how to expedite an Emergency Use Authorization so that they can provide COVID-19 testing and not have to wait for CDC test kits. Do you have any advice or contacts to help answer or support such a request?

Much appreciated and as always sending you my best wishes.

June
Sent from Mail for Windows 10
Denise, I’m sorry I didn’t reply to your question below. I’ve been on calls much of the afternoon so have only a few updates (not all high level):

I don’t have additional details, but let me see if I can get in touch with Seth now to find out more.

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Brooke

From: Jonas, Seth H. EOP/NSC
Sent: Thursday, March 12, 2020 3:04 PM
To: (b)(6) Glenn, Robert <Robert.glenn@fema.dhs.gov>; (b)(6) Polowczyk, John P RADM USN JS J4 (USA); (b)(6) OBERIEN, Kristina M SES JS J4 (USA); (b)(6) Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA); (b)(6) LaBreque, Michael F (Mike) COL US ARMY DLA LOGISTICS OPERATIONS (USA); (b)(6) Peck, Travis G MAJ US Army DLA LOGISTICS OPERATIONS (USA); (b)(6) Brown, Christopher K. - OSHA; (b)(6) OLSZOWKA, Adam R (Beijing) FDA-OSJ I-FOIA-2020-3541_00004956; (b)(6) Abbott, Christopher J. EOP/WHO; (b)(6) Crozer, William F. EOP/WHO; (b)(6) Blum, Mathew C. EOP/OMB; (b)(6) David.Short@dot.gov; (b)(6) Dubray, Michael R (Wuhan); (b)(6) Nicole.Bambas@dot.gov; (b)(6) Benjamin Carlson; (b)(6) Bedan, Morgan E. EOP/WHO; (b)(6) LaBreque, Michael F
Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCCWG) is going through some administrative changes. Tomorrow’s meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

Path forward for the SCCWG

The SCCWG has been chartered as a Policy Coordination Committee (PCC) and will transition accordingly. We plan to kick off the PCC next week with an in-person meeting for principal members of the PCC. The first PCC will cover, among other things, the structure and path forward, ensuring we have appropriate coverage across all lines of effort. By tomorrow (Friday, 03/13/2020) COB, could you please reconfirm who the principal member is for your agency.

Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

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

From: Jonas, Seth H. EOP/NSC
Sent: Wednesday, February 26, 2020 3:15 PM
To: Jonas, Seth H. EOP/NSC  
Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC; Butterfield, Nicholas W. EOP/WHO; Abbott, Christopher J. EOP/WHO; Farquharson, Christine E. EOP/OMB; Carter, Hillary H. EOP/NSC; DL NSC Resilience; Crozer, William F. EOP/WHO; Garufi, Marc A. EOP/OMB; Baehr, James S. EOP/WHO; Williams, James H. EOP/WHO; Merkel, Theo W. EOP/WHO; Blum, Mathew C. EOP/OMB; jon.krohmer@dot.gov; Olszowka, Adam R (Beijing); david.short@dot.gov; Dubray, Michael R (Wuhan); Nicole.Bambas@dot.gov;
Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecoi (b)(6)

COV-Supply Chain Coordination Working Group.

Will update and agenda and read aheads become available
Good afternoon all,

Please see the attached COVID-19 Daily Guidance Update for 12Mar20. If you have any questions, comments or concerns, please contact CAPT Perdue.

This notification was sent to the COVID-19 PMO distribution list.

Very Respectfully,

Secretary’s Operations Center
U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave. S.W.
Washington, D.C., 20201
Office (202) [b](6) ... Fax: 800-514-4256
Email: hhs.soc@hhs.gov

Data enclosed in this email are subject to the Privacy Act of 1974, as amended. Contents shall not be disclosed, discussed, or shared with individuals unless they have a direct need-to-know in the performance of their official duties. Unauthorized disclosure of this information may result in civil or criminal penalties.

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UNCLASSIFIED // FOR OFFICIAL USE ONLY
HHS International SPOTREP: COVID-19 (Update #157)

What: Please see the attached COVID-19 Senior Leader Brief for 12Mar20 for more information.

When: 12Mar20 1830ET

Where: International

Why: CIR: Disease – International

Actions/Follow-Up: The SOC will continue to monitor this incident and report as needed. This message was distributed to the 2019 nCoV IMT, 2019 nCoV Interagency, 2019 nCoV IST, 2019 nCoV Senior Leadership Distribution Lists.

Prepared by: Brian Pittman, Watch Officer
Approved by: Brandon W. Britton, Senior Watch Officer

Secretary’s Operations Center
U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave S.W.
Washington D.C. 20201
Office: (202) ___(b)(6)____
Fax: 800-514-4256
Email: hhs.soc@hhs.gov

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Attached are talking points and information from today. Will send earlier tomorrow.
Thanks for the information Brooke. You’re well-suited to represent us at the meeting as you’ll receive information from each center in the WG meetings. Please let us know how we can best support you.

Best,

Denise

---

Hi Keagan and Denise,

I just spoke with Seth Jonas from the SCCWG. The NSC is still working to finalize the administrative aspects, but here’s what they have so far:

(b)(5)

Thanks,

Brooke

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:31 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: Re: COV-Supply Chain Coordination Working Group
Is this a daily in person meeting? Brooke is the one that understands this and is a part of it. A/S level is stretched thin. Would like to understand why they are elevating.

Sent from my iPhone

On Mar 12, 2020, at 3:24 PM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Thanks Brooke. Keagan, Anand and I will touch base today and provide a response to you and Seth. Any updates from today?

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Thursday, March 12, 2020 3:18 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: COV-Supply Chain Coordination Working Group

Hi Keagan and Denise,

As described below, the NSC Supply Chain Coordination WG is transitioning to become a PCC. By tomorrow (Friday, 03/13/2020) COB, we need to reconfirm who the principal member will be for FDA. Generally, PCCs should be attended at the Assistant Secretary level, so it seems to make sense for one of you to be the new principal. However, I’m happy to help support your efforts on this moving forward and have TS clearance if you were to ever need extra coverage.

Thanks,
Brooke

From: Jonas, Seth H. EOP/NSC 
Sent: Thursday, March 12, 2020 3:04 PM
To: Glenn, Robert <Robert.glenn@fema.dhs.gov>; OBRION, Kristina M S ES JS J4 (USA) <kristina.mair@hhs.gov>; Kless, David Ronald SES DLA LOGISTICS OPERATIONS (USA) <David.Kless.Michael.F(Mike)COLUSARMDLALOGISTICSOPERATIONS(USA)>
Peck, Travis G MAJ USARMDLALOGISTICSOPERATIONS(USA) <Travis.PeckCOLUSARMDLALOGISTICSOPERATIONS(USA)>

Cc: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: COV-Supply Chain Coordination Working Group

Dear All,

The Supply Chain Coordination Working Group (SCWG) is going through some administrative changes. Tomorrow’s meeting of the SCCWG will be cancelled in favor of a restricted working group to discuss a specific issue.

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Generally, PCC should be attended at the Assistant Secretary level.

Thanks,
Seth.

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

From: Jonas, Seth H. EOP/NSC
Sent: Wednesday, February 26, 2020 3:15 PM
To: Jonas, Seth H. EOP/NSC; Glenn, Robert; Polowczyk, John P; Radin, Kristina M; Peck, Travis G; Brown, Christopher K. - OSHA; S60.Policy@dot.gov; matthew.smith@hhs.gov; jessica.falcon@hhs.gov; kevin.cooper@hhs.gov; Bryan.Shuy@hhs.gov; Kristin.deBord@hhs.gov; Zebley, Kyle (HHS/OS/OGA); Marston, Hilary (NIH/NIAID) | E; Heather.Trew@treasury.gov; Paul.Ahern@treasury.gov; laura.wolf@hhs.gov; saa1@cdc.gov; alexis.haakensen@trade.gov; Bartosh, Ernest (Federal); Edens, Mandy - OSHA; Nazak.Nikakhtar@trade.gov; boq1@cdc.gov; Hanson, Elizabeth A Col USAF JS J4 (USA); Brooke.Courtney@fda.hhs.gov
Cc: Waterman, Paige E. EOP/OSTP; Lin, Merry S. EOP/WHO; Watson, Ian D. EOP/OSTP; Davis, May M. EOP/WHO; Honeycutt, Maria G. EOP/OSTP; Sinclair, Michael R. EOP/NSC; Hoelscher, Douglas L. EOP/WHO; Goel, Andrea L. EOP/OMB; Chafin, Kelly B. EOP/NSC; Ferro, Phil J. EOP/NSC; Fabina, Lauren C. EOP/NSC; Rubini, Jeffrey H. EOP/NSC;

---
Subject: COV-Supply Chain Coordination Working Group

When: Friday, March 13, 2020 10:30 AM-11:30 AM (UTC-05:00) Eastern Time (US & Canada).

Where: EEOB Rm 428 or Telecor

Will update and agenda and read aheads become available
Don Demers

Pillai

Denise

RADM Denise M. Hinton
Assistant Surgeon General
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090
Thanks, Denise!

No apology necessary. We prefer you represent – thank you!

Also, I’m sorry I’ve been tied up today and haven’t yet

(b)(5)

I hope we all do! Thank you

Thanks, and I hope you can get some downtime this weekend!

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 6:25 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FW: News from call with McKesson

From: Lutter, Randall <Randall.Lutter@fda.hhs.gov>
Sent: Friday, March 13, 2020 5:40 PM
Good afternoon: You asked for news from my call with McKesson today. CDRH and Brooke Courtney are also informed.

**Early Surveillance of Emerging Shortages**

1. Nasopharyngeal swabs and vials (transportation devices) for complementary testing are in shortage—there is "no inventory" and they are under "severe allocation", i.e., seller-imposed quotas. The shortage derives from conventional flu testing but it implies there may be no capacity to do additional COVID testing, because these swabs and vials are essential for such testing. Orders are running about double last year's levels. 

2. Rapid Flu and Strep tests: Currently supplies are low. They are concerned that if these tests become required before COVID-19 testing, then supplies would be inadequate.

**PPE**

3. N95 Masks—Currently supplies are low. They are directing customers to HHS to get the 3M product. 

4. Isolation gowns—There is "no inventory". Already have a shortage of higher-level protection gowns (due to prior recall before COVID outbreak), but basic gowns available.

5. Gloves—Still have Nitrile gloves in stock, but concerned that if nursing homes switch to a higher level of protection, there would not be enough of those gloves

**Drugs**

6. IV solutions that are not produced in the U.S. Manufacturers are starting to limit sales, so these are already on allocation.

Best regards,

-Randy

202 308 0104
Dear Tim,

Please find attached a summary of (b)(4) Feel reach out to him at the number or email listed below for further information.

The materials in this message are private and may contain Protected Healthcare Information or other information of a sensitive nature. If you are not the intended recipient, be advised that any unauthorized use, disclosure, copying or the taking of any action in reliance on the contents of this information is strictly prohibited. If you have received this email in error, please immediately notify the sender via telephone or return mail.

Best,
Denise
FYI. Please find attached a one-pager from Mayo Clinic CERSI on Mayo’s resources related to COVID-19. If you would like to connect with Mayo Clinic, please contact Nilay Shah at shah.nilay@mayo.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A
Sent: Monday, March 09, 2020 3:51 PM
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>
Subject: RE: COVID19

FYI. Please find attached a one-pager from Yale University CERSI on Yale’s resources related to COVID-19. If you would like to connect with the Yale University, please contact Joe Ross at joseph.ross@yale.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A
Sent: Sunday, March 08, 2020 7:03 PM
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>
Subject: RE: COVID19

FYI. Russ Altman reached out to me to say that Stanford is in the middle of a crisis. They have a faculty member at the Med School that has tested positive for coronavirus. The school is moving to online classes along with other restrictions. I told Russ not to worry about my request.
I think that this will become more and more prevalent.  

Audrey

From: Thomas, Audrey A  
Sent: Sunday, March 08, 2020 11:59 AM  
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nuggest, Bridget <Bridget.Nuggest@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Blumemelon, Donna <Donna.Blumemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara-Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>  
Cc: Blumemelor, Donna <Donna.Blumemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara-Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; Caleb Alexander <galexan9@jhmi.edu>  
Subject: RE: COVID19

As requested, I have reached out to the CERSls for information on their resources related to COVID-19. I just received a one-pager from the University of Maryland CERSI, Baltimore Campus. If you would like to connect with the University of Maryland, please contact James Polli at jpolli@rx.umaryland.edu (copied on this email).

Thanks.

Audrey Thomas

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>  
Sent: Sunday, March 08, 2020 9:17 AM  
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nuggest, Bridget <Bridget.Nuggest@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Blumemelon, Donna <Donna.Blumemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara-Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; William Bentley <bentley@umd.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>  
Cc: Blumemelor, Donna <Donna.Blumemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara-Smith@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>  
Subject: RE: COVID19

Many thanks Audrey.

I shared with our CoV coordinator in CBER and we both think it would be great if you could reach out to each of the CERSIs with a similar request. Can’t hurt to be more aware of all potentials out there.
Also, I’m assuming you are sharing the information with OCET as well.

Carolyn

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>
Sent: Sunday, March 8, 2020 7:25 AM
To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>
Subject: FW: COVID19
Importance: High

FYI. As per discussion at Thursday’s Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU’s resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.
Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader
UCSF-Stanford CERSI Program Official (PO)
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20903
301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>
Sent: Saturday, March 07, 2020 8:46 PM
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>
Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: COVID19
Importance: High

Hello Colleagues,
Here is a one pager describing some Johns Hopkins’ resources that may be relevant to FDA’s COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc’d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH’s Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA’s response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu
To: Shuren, Jeff /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIOBF23SPDLT]/cn=Recipients/cn=44335a0c2f834535bc8713df643905e-Jeff.Shuren]; Marks, Peter /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIOBF23SPDLT]/cn=Recipients/cn=dbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Schwartz, Suzanne /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIOBF23SPDLT]/cn=Recipients/cn=60fbac0e12a24633b1018181711f7849-Suzanne.Sch]; Cho, David S (CBER) /o=ExchangeLabs/ou=Exchange Administrative Group [FYDIOBF23SPDLT]/cn=Recipients/cn=d47af9d991af4c1bf7cb4c1d287f83e-ChoD]
Subject: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

From: Kumar, Dinesh <Dinesh.Kumar@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:36 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Cc: Raza, Mark <Mark.Raza@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Busch, Marcy <Marcy.Busch@fda.hhs.gov>
Subject: RE: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing

Adding Mark, Claire, and Marcy for OCC.

Thanks,
Dinesh

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Sunday, March 15, 2020 3:31 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>; CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Subject: FOR URGENT REVIEW BY 4:30 PM: Remarks for HHS Briefing on COVID Testing
Importance: High

Hello all,

Sharing, on Stephanie's behalf, Dr. Hahn's remarks for the HHS briefing this evening on COVID testing for urgent review by 4:30 p.m. OMA tried to use as much previously cleared content as possible.

The document for concurrent review is available in SharePoint: http://sharepoint.fda.gov/orgs/OC-OEA/OMA/Comms%20for%20Editing/opening%20remarks%20drive%20by%20testing.docx

Thank you,

Michael

Michael Felberbaum
Senior Advisor
Hi – sorry for short notice – any input before Michael Felderbaum sends to Dr. Hahn?

Thanks,

D
Tell me if you’re already receiving these.

Thanks,

Denise

HHS COVID-19 Operational Update Brief

Dial-in information: 212 (b)(6) Passcode (b)(6)

Frequency: M-F

Time: 0815ET

Agenda:
- Opening Comments
- Priorities and Objectives
- Operational Activities
- Planning Activities
- Scientific Priorities
- Healthcare System
- Supply Chain
- Messaging
- Public Reaction
- Activated ESF and LNO Updates
- New Guidance and Policies
- Primary Inter/Intra-Agency Agreements
- Meeting Wrap-Up and Closing Comments

Prepared by:

Secretary’s Operations Center
U.S. Department of Health and Human Services (HHS)
Assistant Secretary for Preparedness and Response (ASPR)
200 Independence Ave., S.W.
Washington, D.C. 20201
Office: (202) 619-7800
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Attached is the FDA-cleared statement that’s with HHS.

Michael Felberbaum
Senior Advisor
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 240-402-9548
michael.felberbaum@fda.hhs.gov
From: McWilliams, Carly

Sent: 3/16/2020 11:36:39 AM

To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>

CC: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>

Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

See below: taken from statement and attached are talkers from last night.
(b)(5)
(b)(5)
Subject: URGENT NEED INFO ON CDRH ACTIONS

I need to get hahn talking points in 15 minutes on actions cdrh is taking.
Also latest numbers if he needs them: shout out to OL for the update.

Since March 2, over 10.4 million tests have become available for the U.S. market, including over 8.28 million tests last week alone.

Two tests had generally been performed per person up to now, but new CDC guidance generally allows just one test to be sufficient for a person not including controls.

Good Morning, thank you for joining today. I know there is a lot of focus and interest on what FDA is doing to combat covid 19 and specifically our work on diagnostics.
I can assure that that we have been working tirelessly throughout this coronavirus outbreak to support efforts across the government to address and mitigate this outbreak.

Those efforts include facilitating the availability and distribution of diagnostic tests, such as the updated policy we are issuing today.

- I know there has been some confusion and concern around the availability of diagnostics. It’s important for the public to understand the role of diagnostics in emergencies and why this particular situation has been different than past outbreaks. And I appreciate you being on the phone today to understand what we are doing and the resources we have available to support labs and grow testing capacity.

I am going to talk specifically on the actions we are taking now:

- First, we are putting in place a policy that gives states the option to take responsibility for tests developed in their states. Similar to the action the FDA granted to the New York State Department of Health last week, states can take responsibility for overseeing tests developed and used by laboratories in their states. States can set up a system in which the state takes responsibility for authorizing such tests, and the laboratories will not engage with the FDA. The system does not need to mirror that of New York. Laboratories developing tests in these states can engage directly with the appropriate state authorities, instead of FDA. Nor will these laboratories be pursuing an EUA with FDA.

- Second, we are expanding who the policy outlined in the Feb. 29 guidance applies to - the policy issued on Feb. 29 was originally applicable only to laboratories that are certified to perform high-complexity testing consistent with requirements under the Clinical Laboratory Improvement Amendments.

- Under the update published today, the agency will not object to commercial manufacturers distributing and labs beginning using new commercially developed tests prior to FDA granting an EUA,
under certain circumstances. We are aware that numerous commercial manufacturers are developing tests for coronavirus with the intention of submitting an EUA to FDA.

- During this public health emergency, FDA does not intend to object to the distribution and use of these tests for specimen testing for a reasonable period of time after the manufacturer’s validation of the test and while the manufacturer is preparing its EUA request where the manufacturer provides instructions for use of the test and posts data about the test’s performance characteristics on the manufacturer’s website. FDA believes that 15 business days is a reasonable period of time to prepare an EUA submission for a test whose performance characteristics have already been validated by the manufacturer.

- Finally, our updated policy provides recommendations for test developers who may wish to develop serological tests for use during this coronavirus outbreak. Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection. We recognize that serology tests are less complex than molecular tests and are solely used to identify antibodies, which limits their effectiveness for diagnosis; however, as stated in the updated guidance, the FDA is not objecting to the distribution and use of serology tests to identify antibodies to SARS-CoV-2 where the test has been validated, notification is provided to FDA, and warning statements are included with the tests, for example, noting the test has not been reviewed by the FDA and positive results may be due to a past or present infection with a different coronavirus strain.

**FDA Support of Diagnostics**

- The FDA has engaged with more than 100 test developers since the end of January, providing templates and advice about the Emergency Use Authorization process. More than 80 developers have sought our assistance with development and validation of tests they plan to bring through the EUA process.
• We are keeping frequently asked questions updated for labs and test developers, providing information on alternative sources of reagents, extraction kits, swabs and more.
• We’ve also set up a toll-free line, 1-888-INFO-FDA, to help labs with any questions they may have about the EUA process, our policies, or getting supplies.
• We know that people want to know the current numbers of tests in the field and how many patients are being tested. This number fluctuates daily as more and more test developers get their tests in the field and start testing patients. At this time FDA is focused on making sure tests are distributed and that test developers and labs have the materials they need to run the tests.
• The FDA continues to maintain operations 24/7 and we are here to support laboratories and test developers as they distribute tests through the country during this time of urgent need.

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:11 AM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: RE: URGENT NEED INFO ON CDRH ACTIONS

Attached is the FDA-cleared statement that’s with HHS.

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

U.S. FOOD & DRUG ADMINISTRATION

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 16, 2020 11:10 AM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Kahn, Jeremy <Jeremy.Kahn@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>
Subject: URGENT NEED INFO ON CDRH ACTIONS

I need to get hahn talking points in 15 minutes on actions cdrh is taking.
From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Monday, March 16, 2020 2:34 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: Re: Corona Testing

Thanks Lowell. I'll get this to the WH Taskforce

From: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Date: March 16, 2020 at 2:32:16 PM EDT
To: COVID-19 IMG <COVID19IMG@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Anderson, Erika <Erika.Anderson@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Yiannas, Frank <Frank.Yiannas@fda.hhs.gov>
Subject: FW: Corona Testing

All,

I received a call, and the email below, from the Food Marketing Institute (trade association for supermarkets/grocery stores). They have members who would like to offer retailer parking lots as testing sites. Can we provide them information or a point of contact?

Also, please note that FMI is hosting daily COVID-19 calls with their industry, and they have offered this forum as a way for FDA to communicate broadly with this industry, if helpful.

Best,
Lowell

From: Peter Matz [FMI] <pmatz@fmi.org>
Sent: Monday, March 16, 2020 1:48 PM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: Corona Testing

Hi Lowell, as I mentioned, there is a lot of interest from FMI supermarket companies in particular re participating in the partnership announced over the weekend whereby COVID-19 testing will take place in certain retailer parking lots nationwide. The President mentioned Walmart, Target and others before requesting additional volunteers. We have several companies asking how they can learn more and offer their assistance. I understand there may be an MOU
through HHS, but I haven’t seen anything so I can’t be sure. Any guidance or thoughts you may have would be greatly appreciated. Thank you!

Separately, we are hosting daily COVID-19 conference calls with our industry and we have invited other groups to join as well, so pls don’t hesitate if FDA ever has any updates or would like to solicit feedback on corona-related challenges or response efforts.

Again, many thanks,
Peter

Peter Matz
Director, Food & Health Policy
FMI - The Food Industry Association
Direct 202.220.0805
Cel (b)(6)
www.fmi.org
Good afternoon,

Attached are my notes from the 3/16/20 AEG meeting, which has been uploaded in the COVID-19 AEG SharePoint subsite.

Tanya E. Malais
Planning Section Chief
2019 Novel Coronavirus (nCoV) IMG
Office: 949-608-2984...
Mobile: [____(b)(6)____]
Planning Section Email: 2019-nCoVFDAIMGPlanning@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

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Subject: (FYD10H23SPDLD/OU=RECIPIENTS/CN=85FECA0BE0694803BE 6030E97C7B4ADB-HINTOND)

RE: Arriving in 30 minutes!!! COVID-19: SNS import of unapproved test kits & masks

Have attachment?

Subject: FW: Arriving in 30 minutes!!! COVID-19: SNS import of unapproved test kits & masks

See below – 564B

Subject: COVID-19: SNS import of unapproved test kits & masks

Dear Carol, John, and Ruth,

John, many thanks again to you and Gayle for your guidance on (b)(3) 42 USC 247d-6b(d)

(b)(3) 42 USC 247d-6b(d)
Additional information from the SNS about these products and shipment is attached. If you have any questions, please don’t hesitate to let us know (CDRH and OCC are copied). We’ll be sure to provide you with any updates we might receive. Many thanks in advance for your time.

Kind regards,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Monday, March 16, 2020 1:49 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: donated test kits, masks

From: Gorman, Susan (ASPR/SNS) <spg4@cdc.gov>
Sent: Friday, March 13, 2020 4:25 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Adams, Steven A (CDC) <saal@cdc.gov>
Subject: RE: donated test kits, masks

Hi Brooke,

The test kit info is attached. Current shipment for test kits will be for (b)(4) and a follow on shipment in about a week for another (b)(4).

A. Flight Information
(b)(4)

B. Shipment Information
Total volume to the US: (b)(4)

1. (b)(4)

2. (b)(4)

There is some other paperwork & info that will be forthcoming

Sue

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 4:08 PM
To: Gorman, Susan (ASPR/SNS) <spg4@cdc.gov>
Cc: Adams, Steven A. (ASPR/SNS) <saal@cdc.gov>
Subject: RE: donated test kits, masks
Hi Sue,

Thank you! Do you have the manufacturer name of the test kits and do you know what type of PPE (surgical masks only? manufacturer)? I’m going to give our import leadership a heads up now.

Thanks,
Brooke

Hi Brooke,
We expect to have the shipment information to you today – Steve will be sending it soon
Thank you
Sue
Sending FYSA so you have full information for reference.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Friday, March 13, 2020 5:37 PM
Subject: COVID-19: SNS import of unapproved test kits & masks

Dear Carol, John, and Ruth,

John, many thanks again to you and Gayle for your guidance on the recent HHS Strategic National Stockpile (SNS) import question. We now have another import for the SNS that is moving fast and expected to arrive in the U.S. on March 17.

(b)(3) 42 USC 247d-6b(d)
Additional information from the SNS about these products and shipment is attached. If you have any questions, please don’t hesitate to let us know (CDRH and OCC are copied). We’ll be sure to provide you with any updates we might receive. Many thanks in advance for your time.

Kind regards,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) (b)(3) 42 USC 247d-6b(d)
brooke.courtney@fda.hhs.gov
Hi Denise,

I am doing my best to track down the correct person and I don't believe there is anyone higher up than you for this.

If you can be of assistance, let me know what I need to do or how you can help.

Thank you again and I hope to hear back from you,

Greg Maselli
Dear Mrs. Hinton:

My company is a product development and manufacturing management firm located in California. We work with food and medical technology companies here, in the US and in China. We are representing a medical device company located in China who has developed a rapid COVID-19 at home test kit. This device is not yet certified with the FDA and we are seeking to have this device COVID-19 lgG/lgM Rapid Test Kit authorized under the Emergency Use Authorization (EUA) to import and market these kits in the United States. Below is a brief description of the device.

**INTENDED USE**

COVID-19 IgG/IgM Rapid Test Kit(Whole Blood/Serum/Plasma) is a solid phase immunochromatographic assay for the rapid, qualitative and differential detection of IgG and IgM antibodies to 2019 Novel Coronavirus in human whole blood, serum or plasma. This test provides only a preliminary test result. Therefore, any reactive specimen with the COVID-19 IgG/IgM Rapid Test Kit (Whole Blood/ Serum/ Plasma) must be confirmed with alternative testing methods and clinical findings.

This manufacturer has performed a clinical study and a white paper is available. They have products that are actively registered with the FDA. Since this device is so new, we are pending the 6-9 weeks of FDA approval. Knowing that this is an urgent situation in our country, I felt it was appropriate to contact you directly. We have several million units ready for import, but we need to make sure the approval goes through the correct channels.

We have found one other factory with a listed FDA number manufacturing a similar test. The device can be found on the FDA site (link below) and it appears to be granted under the EUA


Attached are some pictures of the device along with the step by step explanation of performing the test. We are requesting that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the COVID-19 IgG/IgM Rapid Test Kit to enable the immediate importing and marketing of these devices.

I want to thank you for your service and consideration in helping us. I am seeking your assistance with navigating the authorization to import and market these kits. We are uncertain under the new regulations for EUA and the importing of medical products such as these. I found your contact when researching the COVID-19 FDA website and your authorization to Thermo Fisher Scientific, Inc. (Thermo Fisher) for their TaqPath COVID-19 Combo Kit.
How should we proceed?

Sincerely yours,

Grant Stafford
Principal,
117 Global LLC
Good morning Bill and Tucker,

Please see the attached documents for your situational awareness. Note that the Situation Report (in WORD), prepared by the Incident Management Group (IMG) has CCl and should not be shared further. The IMG is led by our Agency Incident Commander, Michael Mair.

Also, note the FDA has operationalized a diagnostics 24/7 call center. It will be manned by PHS officers that are trained up on specifics to what is happening with COVID-19 on the lab and diagnostics front.

 Those needing assistance can call 1-888-INFO FDA (463-6332) or email COVID19DX@fda.hhs.gov.

Hope you find the information useful.

Best,

Denise
Thanks for the email and it is indeed helpful to include Michael Mair as the IMG Agency Incident Coordinator on these discussions, as much as possible, for situational awareness and in order to facilitate responses with the Center’s lead.
No need to apologize! These are exceptional times. We all got on a call and sorted this out.

Patrizia

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Date: March 18, 2020 at 9:31:06 AM EDT
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>, Guram, Jeet <Jeet.Guram@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>, Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: materials for 3/18 Internal Confidential Deliberative

Apologies on process – I was not attempting to work this issue here

(b)(5)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Roberts, Rosemary <Rosemary.Roberts@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: materials for 3/18 Internal Confidential Deliberative

(b)(5)

Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Date: March 18, 2020 at 9:14:26 AM EDT
To: Mair, Michael <Michael.Mair@fda.hhs.gov>, McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>, Rom, Colin <Colin.Rom@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>, Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>, Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Hi – with respect the **(b)(5)**

**From:** McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
**Sent:** Tuesday, March 17, 2020 10:39 PM
**To:** Rom, Colin <Colin.Rom@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>
**Cc:** Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>

**Subject:** materials for 3/18 Internal Confidential Deliberative

Good Evening, attached are materials for tomorrow. I have listed EUAs below and we can updated with the latest numbers tomorrow morning. Thanks all.
(b)(5)
Just a quick heads up the NSC just noted they'll be circulating a new EO today for quick review ("Prioritizing and Allocating Medical Products for the Response to COVID-19"). The President just mentioned it during a press briefing, and apparently it's one of the pre-scripted EOs that OGCs clear every 2 years. I'll forward it if I receive it from the NSC, but wanted to give you a heads up if you were to receive it from other channels. There will be a very tight timeline for review.

In addition, given the medical product (and food service, researcher, etc.) movement issues due to curfews in certain states and jurisdictions,

(b)(5)
(b)(5)

Thanks,
Brooke

Brooke Courtney, JD, MPH
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Commissioner
U.S. Food and Drug Administration
301-796-0376 (office) 301-796-0367 (cell)
brooke.courtney@fda.hhs.gov
From: O'Shaughnessy, Jacqueline A
Sent: 3/18/2020 2:41:27 PM
To: Hinton, Denise
Subject: FW: Convert to PDF asap please
Attachments: Chloroquine-OCS_Letterhead.docx; Chloroquine-OCS_Letterhead.pdf

From: Hinton, Denise
Sent: Wednesday, March 18, 2020 2:40 PM
To: O'Shaughnessy, Jacqueline A
Subject: Convert to PDF asap please
Good afternoon Ed,

Please find attached a summary of Dr. Achilefu’s proposed technology for laser inactivation of viruses. Feel reach out to him at the number or email listed below for further information. I can provide you some background if you’d like to touch base.

Samuel Achilefu, PhD, FRSC
Optical Radiology Lab, MIR, WUSM
4515 McKinley Ave, St. Louis, MO 63110

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Best,
Denise

FDA-OSJI-FOIA-2020-3541_00005999
Potential?

Please find attached a summary of Dr. Achilefu’s proposed technology for laser inactivation of viruses. Feel reach out to him at the number or email listed below for further information.

Samuel Achilefu, PhD, FRSC
Optical Radiology Lab, MIR, WUSM
4515 McKinley Ave, St. Louis, MO 63110

(b)(6)

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Best,
Denise
Hi David,

Please find attached a summary of Dr. Achilefu’s proposed technology for laser inactivation of viruses. Feel reach out to him at the number or email listed below for further information. I’m available at any time if you’d like additional background.

Samuel Achilefu, PhD, FRSC  
Optical Radiology Lab, MIR, WUSM  
4515 McKinley Ave, St. Louis, MO 63110

(b)(6)

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Best,

Denise (b)(6)
In follow up to below on the new EO, here is the ask:

(b)(5)

[see signed version] (Action: ALL, by 03/19/2020 @ 1:00 P.M.)

How would you like to coordinate the FDA review?

Thanks,
Brooke
Subject: RE: Interagency Supply Chain Meeting for Wednesday March 18, 1:00pm-2:00pm

All EO has been signed and is now attached.

From: Jonas, Seth H. EOP/NSC
Sent: Wednesday, March 18, 2020 2:54 PM
To: (b)(6)
Cc: (b)(6)

Dear Interagency Supply Chain Group Members,

Please see the SOC and draft docs attached for your consideration.

From: Jonas, Seth H. EOP/NSC
Sent: Tuesday, March 17, 2020 9:03 PM
To: (b)(6)
Cc: (b)(6)

Subject: RE: Interagency Supply Chain Meeting for Wednesday March 18, 1:00pm-2:00pm
Subject: Interagency Supply Chain Meeting for Wednesday March 18, 1:00pm-2:00pm

Sent on behalf of Brian J. Cavanaugh, Senior Director for Resilience Policy and Special Assistant to the President

Good Evening-

Tomorrow, March 18, from 1300-1400, we would appreciate your attendance at an Interagency Supply Chain Meeting co-convened by NSC and NEC.

D/As are encouraged to join by SVTC. Please have your video ops center contact WHSR to ensure connections.

If joining by conference call: Participant dial-in: (202)395-6392

EOP members may attend in person in EEOB Room
Sent: 3/18/2020 7:38:22 PM
To: Slikker, William [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4a9f0126e8423d09e5-Wslikker]; Patterson, Tucker [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]
Subject: HHS International SPOTREP: COVID-19 / FDA SitRep

// FOR OFFICIAL USE ONLY
FYI – from today’s SITREP (Red is CCI info)

- **Sample Collection Swabs and Alternatives:**
  - CDRH has been facilitating the short-term distribution of the nasopharyngeal (NP) swabs here in the US. A military transport is flying swabs from [redacted] to the US to aid with transportation issues. The first shipment arrived this morning in Memphis TN to distribute nationally with the aid of [redacted] non-public information).

(b)(4)

- The FAQ will be updated to include mid turbinate and oropharyngeal (OP) sampling is acceptable, although nasopharyngeal is preferred. This would allow the use of a more standard, shorter swab for sample collection.
- CDRH is also in touch with a domestic supplier of swabs and media that may be able to provide more of their product to domestic customers.

From: Hinton, Denise
Sent: Wednesday, March 18, 2020 9:36 PM
To: Jones, Estella <Estella.Jones@fda.hhs.gov>
Subject: CLOSE HOLD FYSA: Dear Governor.docx

Thanks for info – OCET is working with OPLIA on the following draft document.

Best,

Denise
To: Slikker, William [o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOHF23SPDLT)/cn=Recipients/cn=117de5cb256b4aba9f0126e8423d09e5-Wslikker]; Patterson, Tucker [o=ExchangeLabs/ou=Exchange Administrative Group (FYDIOHF23SPDLT)/cn=Recipients/cn=34e4b6c7b20f4c99b8691c7907864d7d-Tpatterson]

Subject: COVID19 Updates

Good morning Bill and Tucker,

Attached for your situational awareness is the 18 March FDA 2019-nCoV SITREP.

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

Thank you,

Denise & Michael
Please review today's draft all hands. 00 secured clearance with center EOs on the 3rd paragraph detailing reporting requirements.

(b)(5)
Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Hope you are well!

Greetings RADM Hinton,

I hope this find you well and thank you for all your work on COVID-19. I forwarded Dr. Al’s email to COVID taskforce and the office that handles PPE. Please see email below.

Thanks,

Nina

Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT, United States Public Health Service
Deputy Director (Acting)

OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm 4114 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-5494
Nina.Nwaba@fda.hhs.gov

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/s/cdrhcustomerservice?ID=16235&
To: Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; CDRH-EUA-Templates
Subject: RE: N-95 Mask EUA Request

Nina,
Thank you,
Regards,
Dr Al

Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Dept of Health
300 West Preston Street, Rm 202
Baltimore, MD 21201
Al.Romanosky@Maryland.Gov
Phone: 410.767.0823
Fax: 410.333.5000
24/7 Emergency Pager: __________

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From: Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>
Sent: Thursday, March 19, 2020 3:49 PM
To: CDRH-EUA-Templates
Cc: Al Romanosky -MDH- <al.romanosky@maryland.gov>
Subject: FW: N-95 Mask EUA Request

FYI

Nina Mezu-Nwaba, PharmD., MPH., MSc,
CAPT, United States Public Health Service
Deputy Director (Acting)

OHTS: Office of Neurological and Physical Medicine Devices
Office of Product Evaluation and Quality

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From: Al Romanosky -MDH- <al.romanosky@maryland.gov>

Sent: Thursday, March 19, 2020 3:33 PM

To: CDRH-NonDiagnosticEUA-Templates <(b)(6)>

Cc: Bonzagni, Neil <Neil.Bonzagni@fda.hhs.gov>; Echeozo, Kodilichi <Kodilichi.Echeozo@fda.hhs.gov>; Lee, Joy <Joy.Lee@fda.hhs.gov>; L. Shenee’ Toombs <(b)(6)>; Liberatore, Mark <Mark.Liberatore@fda.hhs.gov>; Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; Chen, Peter <Peter.Chen@fda.hhs.gov>; Al Romanosky -MDH- <al.romanosky@maryland.gov>; Christopher Snyder -MDH- <csnyder@maryland.gov>; Nicole Brown <Nicole.Brown@maryland.gov>; Sara Barra -MDH- <sara.barra@maryland.gov>; Sherry Adams -MDH- <sherry.adams@maryland.gov>; Tracy Bryan -MDH- <tracy.bryan@maryland.gov>; Veronica Black -MDH- <veronica.black@maryland.gov>

Subject: N-95 Mask EUA Request

Good afternoon,

The Office of Preparedness and Response is submitting a request to have the Kimberly Clark 46727 and 46728 N-95 respirators added to Appendix B under the recent FDA Coronavirus Emergency Use Authorization for PPE. (See below and attached)

I apologize for sending this to my FDA colleagues but I was unsure how to make sure that this request reaches the FDA offices and divisions required to consult and concur with this request. As always thank you for your time, assistance and dedication in service to the residents of the US.

Warmest regards,

Dr Al

3/16/2020

Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response, Maryland Department of Health
300 West Preston St, Rm 202
Baltimore, MD 21201

RADM Denise M. Hinton
Chief Scientist Food and Drug Administration
25 New Hampshire Ave,
Silver Spring, MD 20903

Re: Request for Consultation and Concurrence
Coronavirus Emergency Use Authorization
Dated 2 March 2020
Dear RADM Hinton,

The Maryland Department of Health (MDH), Office of Preparedness and Response (OP&R) is submitting an Emergency Use Authorization (EUA) request to add Kimberly Clark filtering facepiece respirators (FFRs) to Appendix B: Authorized Respirators as described in the Scope of Authorization Section of the Letter of Authorization (Section II) and pursuant to the Conditions of Authorization in the recent FDA Coronavirus EUA declaration dated 2 March 2020.

As a Strategic Stockpiler of medical supplies, equipment and medications in support of Maryland’s public health and medical stakeholders and partners during disaster and emergency response operations, OP&R is entitled to make this request under Section 2 of the Coronavirus EUA.

OP&R requests consultation with both CDC Chronic Viral Diseases Branch (CVDB) and FDA (Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH), Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

In addition, upon concurrence following this consultation, OP&R requests that Kimberly Clark respirators (N95, Disposable Healthcare Respirator, Flat-Fold, Universal, Models KC46727 (regular size) / KC46827 (Small)) currently listed in OP&R inventory and listed in Appendix A – NIOSH Approved FFRs as of 02-29-20 be added to Appendix B: Authorized Respirators in the FDA Coronavirus EUA.

(b)(5)

However, as a result of increased demand and utilization and restricted supply chain availability, a critical shortage of approved FFRs has occurred during the current coronavirus public health emergency. There are not enough quantities of respiratory protective devices available that comply with FDA’s regulatory authority to meet the needs of the United States healthcare system.

This shortage places healthcare providers a great risk of exposure and illness related to SARS CoV2 infection.

Thus, OP&R petitions for approval of the current on-hand inventory of Kimberly Clark respirators and subsequent use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

The following established facts support OP&R’s request:

- SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;
- On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens as a result of COVID-19.
- Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.
- Based on the totality of scientific evidence available to FDA:
  - it is reasonable to believe that authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages;
  - that known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages, outweigh the known and potential risks of such product;
There is no adequate, approved, and available alternative to the emergency use of the respirators described for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.

- Presidential Emergency Declaration regarding the Coronavirus Public Health Emergency on 13 March 2020.

**Office of Preparedness and Response Data Analysis and Justification for EUA Request**

The Maryland Department of Health, Environmental Health Bureau Medical Director, Dr Cliff Mitchell and the OP&R Medical Director and State Emergency Preparedness Coordinator, Dr Al Romanosky, conducted a review and analysis of ten NIOSH reports detailing the performance results of respirators sampled from ten stockpile facilities.

The NIOSH reports presented testing results following reassessment of 3M, Moldex and Kimberly Clark respirators in long term storage at the stockpile facilities. Drs Mitchell and Romanosky focused on testing results for KC 46727 and KC 76827 N-95 respirators.

Eight of ten warehouse had Kimberly Clark respirators in their inventory. Respirators from a total of 28 samples were tested for a total of 926 respirators (average of 33 respirators collected for each sample tested).

**NIOSH Testing Of N-95 Face Masks**

NIOSH visited ten warehouse locations where PPE is stored as part of the SNS program. Random samples of various N-95 masks were collected from various lots of face masks.

**NIOSH Standard Test Procedures with Pass / Fail Criteria:**

- Inhalation resistance: pass <35 mm H2O column @ 85 LPM
- Exhalation resistance: pass <25 mm H2O column @ 85 liters per minute (LPM)
- Filtration: <5.0% particulate penetration
- Efficiency for N95: (>95.0% filter efficiency)

**Visual Inspection of Containers and Face Masks:**

- no dust or damage to product packaging
- damage to respirator no visible water / chemical exposure

**Storage Conditions with Documented %Relative Humidity and Temperature**

- Temperature / humidity controlled
- Limited sun light / light exposure

OP&R conducted a review of the 10 NIOSH Reports pertaining to the assessment of N-95 Masks following long term storage.

**Findings of NIOSH Reassessment for Kimberly Clark N-95 Respirators**
Number of warehouses containing Kimberly Clark Respirators:

8/10 Warehouses had an inventory of Kimberly Clark masks

Kimberly Clark N-95 Respirators found in the repository samples

KC 46727 (regular size) / KC 46827 (small size)

Total Sample Lots of Kimberly Clark Respirators Tested

28 sample lots selected during sampling (926 total masks tested)

NIOSH N-95 Standard Test Procedure Results for Kimberly Clark Masks

Inhalation Pressure Test: **100% passed (28/28)**

Exhalation Pressure Test: **100% passed (28/28)**

Percent Particulate Penetration Testing / Filtration

**26/28 passed: 95% of particles 03 microns were filtered (pass: 5.0);**

Test target value: Filter 95% of 0.3-micron size particles.

NOTE: CoVid 19 particle size (0.13 microns)

Particle penetration failures: **2/28 lots (33 of 926 Failure: 7% failure rate)**

Failure scores:

5.5 (interpretation that this tested group from a single warehouse had a percent filtration rate of 94.5% (target 95%); 3.5% failure rate

8.0 for a sampling for a single warehouse for a percent filtration percentage of 92%;

Interpretation of The Findings

Following detailed review of the ten NIOSH reports on N-95 face masks selected from ten warehouses, a100% of the Kimberly Clark N-95 face masks passed both the inspiratory and exhalation pressure Standard Test Procedures.
Summary Finding

Based on totality of scientific evidence, it is reasonable belief that the Kimberly Clark respirators will be effective and represent a critical emergency supply critical to Maryland’s response to this public health emergency.

Therefore, it is reasonable to believe that the known and potential benefits of permitting use of the OP&R inventory of Kimberly Clark respirators (800,000+), when used consistently with the Scope of Authorization of the Coronavirus EUA (Section II), outweigh the known and potential risks of such a product.

Terms Following Approval of OP&R Coronavirus EUA Request

Upon approval of our request, OP&R will adhere to the following requirements as delineated in the Coronavirus EUA, IV Conditions of Authorization.

Respirator Labeling

- Authorized Kimberly Clark respirators will be labeled:
  - approved by NIOSH

Adverse Events Reporting

- To the extent feasible given the emergency circumstances, the Office of Preparedness and Response will maintain reports of adverse events received from healthcare personnel and facilities to which the authorized respirators are distributed.
  - Adverse events of which OP&R becomes aware will be reported to FDA via Medwatch Forms for FDA Safety Reporting.

Additional EUA Requests

- OP&R will submit a request to FDA with a copy of the request to CDC (CVSDBadmin@cdc.gov) and specifying the manufacturer, model number, and the product expiry date.
  - Such requests will be made by OP&R in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

EUA Record Keeping and Inspection

- OP&R will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request

EUA Termination

- OP&R utilization of the Kimberly Clark respirators will be effective until:
  - the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.
Existing inventory is depleted.

Thank you in advance for your time and consideration of this request.

Sincerely yours

Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Department of Health

CC:
CDC Chronic Viral Diseases Branch Admin
FDA: Office of Strategic Partnerships and Technology Innovation (OST)
FDA: Center for Devices and Radiological Health (CDRH)
FDA: Division of Infection Control and Plastic and Reconstructive Surgery/CDRH
FDA: Office of Counterterrorism and Emerging Threats (OCET)
FDA: Office of the Chief Scientist (OCS)
FDA: Office of the Commissioner (OC).
Thank you, Dr. Al.

Best,

Denise

---

From: Al Romanosky -MDH- <al.romanosky@maryland.gov>
Sent: Thursday, March 19, 2020 7:37 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: CDRH-NonDiagnosticEUA-Templates <CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov>; CVSDBadmin@cdc.gov; Bonzagni, Neil <Neil.Bonzagni@fda.hhs.gov>; Echeozo, Kodilichi <Kodilichi.Echeozo@fda.hhs.gov>; Lee, Joy <Joy.Lee@fda.hhs.gov>; Liberatore, Mark <Mark.Liberatore@fda.hhs.gov>; Nwaba, Nina C <Nina.Nwaba@fda.hhs.gov>; Chen, Peter <Peter.Chen@fda.hhs.gov>; Christopher Snyder -MDH- <csnyder@maryland.gov>; Nicole Brown <Nicole.Brown@maryland.gov>; Sara Barra -MDH- <sara.barra@maryland.gov>; Sherry Adams -MDH- <sherry.adams@maryland.gov>; Tracy Bryan -MDH- <tracy.bryan@maryland.gov>; Veronica Black -MDH- <veronica.black@maryland.gov>
Subject: Re: N-95 Mask EUA Request

Denise,

good evening,

thank you for the email. I hope everything is going well, all things considered. 

(b)(5)

Please let me know if there is anything I can do to support FDA given that you are primarily located in Maryland.
Warmest regards,
Dr Al

---

Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Dept of Health
300 West Preston Street, Rm 202
Baltimore, MD 21201
Al.Romanosky@Maryland.Gov
Phone: 410.767.0823
Mobile: (b)(6)
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24/7 Emergency Pager: (b)(6)

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On Thu, Mar 19, 2020 at 6:58 PM Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Dear Dr. Al,

(b)(5)

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-1090

From: Al Romanosky -MDH- <al.romanosky@maryland.gov>
Sent: Thursday, March 19, 2020 3:33 PM
To: CDRH-NonDiagnosticEUA-Templates <CDRH-NonDiagnosticEUA-Templates@fda.hhs.gov>; CVSDAdmin@cdc.gov; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Bonzagni, Neil <Neil.Bonzagni@fda.hhs.gov>; Echeozo, Kodilichi <Kodilichi.Echeozo@fda.hhs.gov>; Lee, Joy <Joy.Lee@fda.hhs.gov>; L. Shenee' Toombs <(b)(6)>; Liberatore, Mark
Subject: N-95 Mask EUA Request

Good afternoon,

The Office of Preparedness and Response is submitting a request to have the Kimberly Clark 46727 and 46728 N-95 respirators added to Appendix B under the recent FDA Coronavirus Emergency Use Authorization for PPE. (See below and attached)

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Warmest regards,

Dr Al

3/16/2020

Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response, Maryland Department of Health
300 West Preston St, Rm 202
Baltimore, MD 21201

RADM Denise M. Hinton
Chief Scientist Food and Drug Administration
25 New Hampshire Ave,
Silver Spring, MD 20903

Re: Request for Consultation and Concurrence
Coronavirus Emergency Use Authorization
Dated 2 March 2020

Dear RADM Hinton,

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As a Strategic Stockpiler of medical supplies, equipment and medications in support of Maryland’s public health and medical stakeholders and partners during disaster and emergency response operations, OP&R is entitled to make this request under Section 2 of the Coronavirus EUA.

OP&R requests consultation with both CDC Chronic Viral Diseases Branch (CVDB) and FDA (Office of Strategic Partnerships and Technology Innovation (OST)/Center for Devices and Radiological Health (CDRH), Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC).

In addition, upon concurrence following this consultation, OP&R requests that Kimberly Clark respirators (N95, Disposable Healthcare Respirator, Flat-Fold, Universal, Models KC46727 (regular size) / KC46827 (Small)) currently listed in OP&R inventory and listed in Appendix A – NIOSH Approved FFRs as of 02-29-20 be added to Appendix B: Authorized Respirators in the FDA Coronavirus EUA

These Kimberly Clark respirators are approved by the National Institute for Occupational Safety and Health (NIOSH), in accordance with 42 CFR Part 84, as non-powered air purifying particulate FFRs. Although approved, they have since passed the manufacturers’ recommended shelf-life, for use in healthcare settings by healthcare personnel (HCP).

However, as a result of increased demand and utilization and restricted supply chain availability, a critical shortage of approved FFRs has occurred during the current coronavirus public health emergency. There are not enough quantities of respiratory protective devices available that comply with FDA’s regulatory authority to meet the needs of the United States healthcare system.

This shortage places healthcare providers a great risk of exposure and illness related to SARS CoV2 infection.

Thus, OP&R petitions for approval of the current on-hand inventory of Kimberly Clark respirators and subsequent use in healthcare settings by healthcare personnel to prevent wearer exposure to pathogenic biological airborne particulates during respirator shortages resulting from the Coronavirus Disease 2019 (COVID-19) outbreak.

The following established facts support OP&R’s request:

• SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

• On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens as a result of COVID-19.

• Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS declared on March 2, 2020, that circumstances exist justifying the authorization of emergency use of personal respiratory protective devices during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.

• Based on the totality of scientific evidence available to FDA:
  o it is reasonable to believe that authorized respirators may be effective in preventing HCP exposure to pathogenic biological airborne particulates during FFR shortages;
  o that known and potential benefits of the authorized respirators, when used to prevent HCP exposure to such particulates during FFR shortages, outweigh the known and potential risks of such product;
  o There is no adequate, approved, and available alternative to the emergency use of the respirators described for preventing HCP exposure to such particulates during FFR shortages to prevent disease spread.

• Presidential Emergency Declaration regarding the Coronavirus Public Health Emergency on 13 March 2020.
The Maryland Department of Health, Environmental Health Bureau Medical Director, Dr Cliff Mitchell and the OP&R Medical Director and State Emergency Preparedness Coordinator, Dr Al Romanosky, conducted a review and analysis of ten NIOSH reports detailing the performance results of respirators sampled from ten stockpile facilities.

The NIOSH reports presented testing results following reassessment of 3M, Moldex and Kimberly Clark respirators in long term storage at the stockpile facilities. Drs Mitchell and Romanosky focused on testing results for KC 46727 and KC 76827 N-95 respirators.

Eight of ten warehouse had Kimberly Clark respirators in their inventory. Respirators from a total of 28 samples were tested for a total of 926 respirators (average of 33 respirators collected for each sample tested).

In a letter dated 7 June 2018, Kimberly Clark “recommended disposing of any product that is beyond the established shelf life, has not been stored according to the user instructions, is damaged, does not provide a proper fit, or has missing parts”.

**NIOSH Testing Of N-95 Face Masks**

NIOSH visited ten warehouse locations where PPE is stored as part of the SNS program. Random samples of various N-95 masks were collected from various lots of face masks.

*NIOSH Standard Test Procedures with Pass / Fail Criteria:*

- Inhalation resistance: pass <35 mm H2O column @ 85 LPM
- Exhalation resistance: pass <25 mm H2O column @ 85 liters per minute (LPM)
- Filtration: <5.0% particulate penetration
- Efficiency for N95: (>95.0% filter efficiency)

*Visual Inspection of Containers and Face Masks:*

- No dust or damage to product packaging
- Damage to respirator no visible water / chemical exposure

*Storage Conditions with Documented %Relative Humidity and Temperature*

- Temperature / humidity controlled
- Limited sun light / light exposure

Based upon the findings of the NIOSH evaluation as well as the letter from Kimberly Clark, the recommendations concerning utilization of the Kimberly Clark N-95 face masks was

**(b)(5)**

OP&R conducted a review of the 10 NIOSH Reports pertaining to the assessment of N-95 Masks following long term storage.

**Findings of NIOSH Reassessment for Kimberly Clark N-95 Respirators**

*Number of warehouses containing Kimberly Clark Respirators:*

8/10 Warehouses had an inventory of Kimberly Clark masks

*Range of Long-Term Storage for the N-95 masks*
Kimberly Clark N-95 Respirators found in the repository samples
KC 46727 (regular size) / KC 46827 (small size)

Total Sample Lots of Kimberly Clark Respirators Tested
28 sample lots selected during sampling (926 total masks tested)

NIOSH N-95 Standard Test Procedure Results for Kimberly Clark Masks

Inhalation Pressure Test: **100% passed (28/28)**

Exhalation Pressure Test: **100% passed (28/28)**

Percent Particulate Penetration Testing / Filtration

**26/28 passed: 95% of particles 0.3 microns were filtered (pass: 5.0);**

Test target value: Filter 95% of 0.3-micron size particles.

NOTE: Covid-19 particle size (0.13 microns)

Particle penetration failures: **2/28 lots (33 of 926 Failure: 7% failure rate)**

Failure scores:

5.5 (interpretation that this tested group from a single warehouse had a percent filtration rate of 94.5% (target 95%);

3.5% failure rate

8.0 for a sampling for a single warehouse for a percent filtration percentage of 92%; **3.5% failure rate**

Although, the Kimberly Clark masks failed at two individual warehouses, the other warehouses most likely contained masks produced during the sample productoin period, Therefore, these findings may represent aberrancies and not reflect the whole of the Kimberly Clark N-95 face Masks.

Interpretation of The Findings

Following detailed review of the ten NIOSH reports on N-95 face masks selected from ten warehouses, a100% of the Kimberly Clark N-95 face masks passed both the inspiratory and exhalation pressure Standard Test Procedures.

Therefore, based upon the review of the NIOSH re-assessments and the performance of the Kimberly Clark Masks, I feel that they could be used as N-95 respirators in lieu of current masks which are in extremely short supply.

Summary Finding
Based on totality of scientific evidence, it is reasonable belief that the Kimberly Clark respirators will be effective and represent a critical emergency supply critical to Maryland’s response to this public health emergency.

Therefore, it is reasonable to believe that the known and potential benefits of permitting use of the OP&R inventory of Kimberly Clark respirators (800,000+), when used consistently with the Scope of Authorization of the Coronavirus EUA (Section II), outweigh the known and potential risks of such a product.

**Terms Following Approval of OP&R Coronavirus EUA Request**

Upon approval of our request, OP&R will adhere to the following requirements as delineated in the Coronavirus EUA, IV Conditions of Authorization.

**Respirator Labeling**

- Authorized Kimberly Clark respirators will be labeled:
  - approved by NIOSH

\[\text{(b)(5)}\]

**Adverse Events Reporting**

- To the extent feasible given the emergency circumstances, the Office of Preparedness and Response will maintain reports of adverse events received from healthcare personnel and facilities to which the authorized respirators are distributed.
  - Adverse events of which OP&R becomes aware will be reported to FDA via Medwatch Forms for FDA Safety Reporting.

**Additional EUA Requests**

\[\text{(b)(5)}\]

- OP&R will submit a request to FDA with a copy of the request to CDC (CVSDAdmin@cdc.gov) and specifying the manufacturer, model number, and the product expiry date.
  - Such requests will be made by OP&R in consultation with, and require concurrence of, OST/CDRH, Division of Infection Control and Plastic and Reconstructive Surgery/CDRH, and OCET/OCS/OC.

**EUA Record Keeping and Inspection**

- OP&R will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request

**EUA Termination**

- OP&R utilization of the Kimberly Clark respirators will be effective until:
  - the declaration that circumstances exist justifying the authorization of the emergency use of personal respiratory protective devices during the COVID-19 outbreak is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.
  - Existing inventory is depleted.

Thank you in advance for your time and consideration of this request.
Sincerely yours

Albert J Romanosky MD PhD
Medical Director / State Emergency Preparedness Coordinator
Office of Preparedness and Response
Maryland Department of Health

CC:
CDC Chronic Viral Diseases Branch Admin
FDA: Office of Strategic Partnerships and Technology Innovation (OST)
FDA: Center for Devices and Radiological Health (CDRH)
FDA: Division of Infection Control and Plastic and Reconstructive Surgery/CDRH
FDA: Office of Counterterrorism and Emerging Threats (OCET)
FDA: Office of the Chief Scientist (OCS)
FDA: Office of the Commissioner (OC).
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Hi Bill and Tucker,

Attached for your situational awareness is the 19 March FDA 2019-nCoV SITREP sent by Michael Mair this evening and the daily SOC SitRep.

(b)(5)

Best,

Denise
That’s a great solution – we’ll discuss tomorrow.

Thank you!
Denise

From: Sigg, Jim <Jim.Sigg@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:59 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: FYI: COVID-19 Update: 15 Days to Slow the Spread--Day 4

I do not advise changing it now. We worked long and hard with the centers and that is the rile of occ health. Perhaps occ health can provide a weekly report or summary to him as DASHO. We can discuss tomorrow.

Thanks,
Jim

From: "Hinton, Denise" <Denise.Hinton@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:57 PM
To: "Sigg, Jim" <Jim.Sigg@fda.hhs.gov>
Subject: FYI: COVID-19 Update: 15 Days to Slow the Spread--Day 4

From: Pillai, Segaran <Segaran.Pillai@fda.hhs.gov>
Sent: Thursday, March 19, 2020 8:53 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: COVID-19 Update: 15 Days to Slow the Spread--Day 4

There is nothing mentioned in the message about notification to the DASHO for the agency. How do we fix it?
Pillai

From: A Message from the Commissioner <message@fda.hhs.gov>
Date: March 19, 2020 at 8:42:52 PM EDT
To: FDA-Wide <FDA-Wide@fda.hhs.gov>
Subject: COVID-19 Update: 15 Days to Slow the Spread--Day 4

Dear FDA Team,

The FDA’s work was center stage in today’s White House Coronavirus Task Force press briefing where I had the privilege to discuss some of the critical work currently underway by FDA professionals in combatting the COVID-19 virus. In particular, our efforts to determine the safety and potential effectiveness of certain antiviral medications to treat patients suffering from this virus was the highlight of today.
This is truly a historic time for the world, and one where the FDA has an incredibly crucial role. While we are working at a record pace, I am mindful of the tremendous responsibility that comes with that. As I shared earlier today at the press conference, I recognize the importance of providing hope—and I have great hope and confidence that we will knock down this virus together, but that will never translate into providing false hope because our decision-making will always be driven by data and science.

The health and safety of the FDA community remain a top priority to the FDA Leadership Team. To ensure we safeguard the health of our entire workforce, employees are encouraged to voluntarily notify their immediate supervisor and/or the FDA’s Occupational Health Services at (301) 796-2331 or occupationalhealthservices@fda.hhs.gov as soon as possible if they test positive for COVID-19. Any supervisor contacted by an employee confirming they tested positive for the COVID-19 virus should immediately notify their Center Director and Executive Officer for awareness and necessary action. All personal employee information will be kept confidential. Employees are also encouraged to voluntarily notify their immediate supervisor if they had direct contact with someone outside of work who tested positive for COVID-19 to discuss the use of workplace flexibilities, including telework, if not already in place.

The FDA just issued a nationwide call for blood donations, which have been dramatically reduced due to the implementation of social distancing and the cancellation of blood drives. We can fully support the President’s Coronavirus Guidelines for America while helping to maintain our nation’s blood supply as blood donation centers already have practices in place to facilitate the safe donation of blood and are using additional social distancing precautions. I strongly urge FDA employees to consider donating by making an appointment with their local blood donor center or the Red Cross. #FDAStrong

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs
Good evening,

Attached are my notes from the 3/19/20 AEG meeting.

Tanya E. Malais
Planning Section Chief
2019 Novel Coronavirus (nCoV) IMG
Office: 949-608-2984
Mobile: (b)(6)
Planning Section Email: Tanya.Malais@fda.hhs.gov

24 hour Emergency Number: 1-866-300-4374

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Good morning – compare your notes to these and see how you did.

Thanks,
Denise
FW: Preparing to Issue: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health

Attachments: 20200318-PR--Hand Sanitizer Guidance FINAL wmeta.docx

Preparing to Issue: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health

OMA is preparing to issue the following Press Release: Coronavirus (COVID-19) Update: FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health

This should post here within the next 30 minutes.

Thank you,
--Jeremy

Jeremy Kahn
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Tel 301-795-8571
jeremy.kahn@fda.hhs.gov

FDA-OSJI-FOIA-2020-3541_00006009
Thanks for sharing!

Good morning! 9:30 – 10:30 a.m. **WebEx only.** For first ~30 minutes, we will run down status of current items. 10:00-10:30, will focus on forward look/strategy or the day’s focus topic (will change—let me know if you have a focus topic for the group). List below. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

Green = comms live today. Red = comms pending [confidential until issued/publicized]

**COMMS PIPELINE**— for each item below, chime in on plans for:

- **Press**
- **Social**
- **Other external comms (e.g., consumer, Voices)**
- **Stakeholder**
- **Web**
- **Internal**

**Medical products cross-cutting**
- March 20 web update — Public Health England study expands to apply technology used for an ongoing MCMi, Ebola project to gather important information about COVID-19 infection (PHE press release today noted this FDA funding +[LINK](#))

- **Diagnostics**
  - March 19 – 2 new EUAs (DiaSorin Molecular LLC and GenMark Diagnostics, Inc.) w/tweets
  - March 20 – FDA statement on FDA efforts to warn consumers about companies marketing fake COVID-19 diagnostic tests, including home test kits (joint statement by ORA and CDRH)
  - Date TBD – Hahn/Redfield op-ed on diagnostic testing
- **Other devices**
  - March 20 - FDA statement: Coronavirus (COVID-19) Update: FDA allows for the use of certain non-invasive medical devices to monitor patients’ vital signs remotely, reducing the need for hospital visits and minimizing the risk of exposure to coronavirus
    - New Immediately In Effect Guidance on Remote Patient Monitoring Devices (CDRH)
- **Therapeutics**
  - **OCOMM’s Division of Drug Information (DDI) has received 1,067 total COVID-19-related questions/concerns to date. Consumer (348), Industry (476), HCP (194), Other (49)**
  - Date TBD – Press statement on patient access to certain drugs with a Risk Evaluation and Mitigation Strategy (REMS) during pandemic
- **Vaccines / biologics**
  - March 19 – Updated Instructions for Submitting Lot Release Samples and Protocols for CBER-regulated Products During the COVID-19 Pandemic posted to web
• PPE
  o March 20 – Letter to healthcare providers on conservation strategies for gloves
  o Clinical trial updates
  o Date TBD - AE reporting on clinical trials during the pandemic

• Supply chain / shortage updates cross-cutting
  o ~April 1 - CDER/CBER draft guidance regarding permanent discontinuance or interruption in manufacturing
  o CDER
    ■ March 19 - second hand sanitizers guidance posted: Guidance for Industry: Temporary Policy for Preparation of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency (COVID-19), (in addition to March 14 Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency)
  o Reactive Q&A on these guidances in progress
    ■ March 20 - FDA statement: Coronavirus (COVID-19) Update: FDA provides guidance to compounders on production of alcohol-based hand sanitizer to help boost supply, protect public health
  o CBER
    ■ March 19 – updated web posting to HCT/P establishments on COVID-19 (on hold)
    ■ March 19 – web posting for manufacturers of CBER-licensed biologics regarding changes in lot release
  o CDRH
    ■ March 20 - Ventilator supply strategies for HCPs guidance
  o Press statement in progress
  o Stakeholder emails & outreach to hospitals being developed
  o CFSAN
    ■ Social media @FDAfood to notify about availability of food industry call on March 18
  o CVM

• Inspection delays / travel advisories (ORA)

• UFA deadlines at risk (ORA/Centers)

• Other cross-cutting
  o Daily - Prepared talking points for Commissioner Hahn for daily White House Task Force and press briefing
  o Daily - Prepared/posted tweets/graphics on above topics for Commissioner and FDA accounts
  o Weekly (Wednesdays): COVID-19 response recap emails to stakeholders (~65K)
  o Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA
  o March 19 – Consumer FAQs translated to Spanish & posted
  o March 20 or 23 - FDA Voices on PHS All Hands/role in response
  o March 20 or 23 - message to patients with cancer and their health care providers (Oncology Center of Excellence)
  o Date TBD - Comprehensive press statement on FDA response activities, to provide update on areas including diagnostics, inspections, and supply chain

• Other comms?
  o Promoting WH, HHS, CDC, etc?

MEDIA MONITORING (Anne) - notes on SharePoint

MEETING REPORT OUT (see Op Tempo for dial-in #s)
Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- White House press conference/TF
- AEG discussions
  - Hahn NPR interview this morning

TODAY’S FOCUS DISCUSSION

- Expectations for media inquiries, other deadlines (Lena/all)
- Internal comms regarding talking to outside entities (Lena)
- Hand sanitizers – add contact info to landing page? (Lena)
- Staffing (do you need help?)
- Strategy / forward look
  - Anything from OEA?

Pending, from previous discussions

- FDA outreach to diverse populations (Gloria Sanchez-Contreras, OMA)
- 3D printing issues (CDRH)
- Web language RE travel (“please be advised” box + home page blurb) – Heidi Rebello working on this

Other items for JIC discussion/reference:

- Info for daily WH press briefing – what #s, etc. do we need today?
  - Folder of WHTP
  - OL Q&A SP
- Other hot topics
  - Therapeutics
  - Food supply
  - Consumer inquiries

Reminder when sending review requests to JIC:

- Filename in SharePoint: __________ (no spaces – e.g., 20200319_Blood_supply_stmt)
- Please insert the JIC clearance table at the end of your doc, so JIC & IMG members can quickly mark as reviewed (it lives in the JIC Process folder in SharePoint; also attached to 3/19 a.m. email)

Reviews

Note: This table includes mostly items still in JIC/IMG review, to help JIC/IMG members easily keep track of outstanding reviews. It is NOT a comprehensive list of all pending comms. (Short turnaround reviews that happen after ~4 p.m. with deadlines before ~9 a.m. the following day are not included.)

<table>
<thead>
<tr>
<th>Comm</th>
<th>Clearance Due</th>
<th>Contact (JIC)</th>
<th>Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)</th>
<th>Center(s) Responsible</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>White House TPs (folder – new location)</td>
<td>Daily by 12 pm (time may vary)</td>
<td>Stephanie Caccamo/Carly McWilliams</td>
<td></td>
<td>All</td>
<td>Note: These do evolve and shift throughout the day as we are asked to add additional content.</td>
</tr>
<tr>
<td>Comm</td>
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<tr>
<td>InsideFDA FAQs for employees</td>
<td>March 5</td>
<td>Tina Harrison</td>
<td>OGC/GLD (clearing OO/HR Q&amp;As, at OCC request)</td>
<td>JIC/IMG</td>
<td>JIC reviews completed March 6; with Tania Tse for GLD clearance</td>
</tr>
<tr>
<td>Consumer response letter</td>
<td>TBD (revised letter)</td>
<td>April Finnen / Anne Norris</td>
<td>Rewrite</td>
<td></td>
<td>Rewrite to respond from RADM Hinton (ExecSec noted policy that Dr. Hahn does not respond to consumer letters; letter was written from Dr. POV).</td>
</tr>
<tr>
<td>FDA Voices on PHS all hands/response support</td>
<td>TBD</td>
<td>Brooke Leggin</td>
<td>HHS</td>
<td></td>
<td>Target date for publication is 20 Mar</td>
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<tr>
<td>Reps. Rose and Reed letter on high throughput testing of COVID-19 Samples</td>
<td>March 19 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CDRH</td>
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<tr>
<td>Rep. Porter letter on COVID-19 testing</td>
<td>March 20 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CDRH</td>
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<tr>
<td>Sen. Thom Tillis letter on COVID-19 testing</td>
<td>March 20 COB</td>
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<td>JIC/IMG</td>
<td>CDRH</td>
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<td>Sens. Warren/Murray letter on including pregnant and lactating women in COVID-19 vaccine clinical trials</td>
<td>March 23 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CBER, OMH, OWH</td>
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<tr>
<td>Rep. Perlmutter letter on antiviral drugs</td>
<td>March 25 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CDER/CBER</td>
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<tr>
<td>E&amp;C Oversight Nasal Swab Inquiry</td>
<td>March 25 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CDRH</td>
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<td>Sen. Gardner letter re EUAs/testing</td>
<td>March 25 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CDRH</td>
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<td>Sen. Blackburn drug inquiry</td>
<td>March 26 COB</td>
<td>Caitlin Pennington/ Matthew Lockheed</td>
<td>JIC/IMG</td>
<td>CDER</td>
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<td>Rep. Zeldin letter re COVID-19 testing</td>
<td>March 26 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDER</td>
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<td>Rep. Beyer letter on COVID-19 testing</td>
<td>March 30 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDRH</td>
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<td>Rep. Carter letter on compounding</td>
<td>March 30 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDER</td>
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<tr>
<td>HGSAC Minority f/u briefing questions related to medical product supply chain</td>
<td>March 25 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDRH, CDER, and ORA</td>
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<tr>
<td>Foreign Inspections/COVID-19 Questions from Briefing with bipartisan House E&amp;C staff</td>
<td>March 25 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
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<td>Food &amp; Feed Inspection and Food Waste Q&amp;A</td>
<td>March 23 COB</td>
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<td>JIC/IMG</td>
<td>CFSAN, CVM, and ORA</td>
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<tr>
<td>National Governors Association Questions re drug supply chain and diagnostics</td>
<td>March 24 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDRH &amp; CDER</td>
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<td>Remdesivir question from Sen. Toomey’s office</td>
<td>March 23 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDER</td>
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<tr>
<td>Follow up questions from E&amp;C Briefing</td>
<td>March 23 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDER</td>
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<td>IND Question from Congressional fellow</td>
<td>March 26 COB</td>
<td>Caitlin Pennington/ Matthew LOCKEED</td>
<td>JIC/IMG</td>
<td>CDER</td>
<td></td>
</tr>
</tbody>
</table>

**FUTURE COMMS**

| Daily tweets (including evergreen + weekends) | Daily before 3:00 p.m. | Abby Capobianco / Erin Ruberry | All | Ongoing: time-sensitive Commissioner tweets need to be AEG-cleared before 3:00 p.m. daily | |

FDA-OSJI-FOIA-2020-3541_00005967
April Finnen
IMG JIC Lead
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)
U.S. Food and Drug Administration
Desk: 240-402-0470
EOC: (b)(6) (hours at EOC Mon. & Thurs. 9 a.m. – 11:30 a.m., 1 p.m. – 3 p.m.)
Cell: Call this # or IM/Skype to reach me
Email: april.finnen@fda.hhs.gov
JIC (Joint Information Center) email: 2019-nCoVFDAIMGJIC@fda.hhs.gov

WORKING COPY of the TPs (this week)  NEW – daily by 3 p.m. JIC input  Siobhan Delaney  JIC/IMG  All

Comm  Clearance Due  Contact (JIC)  Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)  Center(s) Responsible  Notes

FDA-OSJI-FOIA-2020-3541_00005968
Indeed. We did fund ARA to look at N95 decontamination, and people have been asking for a copy of the resulting report documenting the research (attached). Long story short...there was some concern about disseminating widely without knowing who was receiving it, but it is a public document and circumstances have shifted things in the direction of making it freely available. The report is attached.

I'm not aware of any recent interactions with the DepSec on this....but copying RADM Hinton and Michael Mair because they may have more visibility.

Robert,

Do you recall from several years ago when we had an MCMi BAA solicitation regarding N95 decontamination to enable reuse whether we received a quad chart or a proposal from Battelle? Something sticks in my head but I can't recall the details.

I know we awarded contract to ARA/Brian Heimbuch for similar work but wasn't sure of the level of interaction we had with Battelle on their approach.

I ask because they are interacting with the DepSec Hargen and our SMEs in CDRH are now engaged in that discussion to determine if there is a viable reg path forward for them to proceed, and we have a call set up with them for 10:30am.

Apparently, they mentioned at the DepSec call interacting with OCET in the past and I have vague recollections as well, but not sure how much data we had ever seen and vetted.

Whatever insight you can provide would be helpful here.

Suzanne B. Schwartz, MD, MBA  
Deputy Director (Acting Office Director) Office of Strategic Partnerships & Technology Innovation  
Center for Devices and Radiological Health (CDRH)  
Office of Strategic Partnerships and Technology Innovation (OST)  
U.S. Food and Drug Administration  
WO66, Room 5410  
Tel: 301-796-6937  
Cell: (b)(6)  
Suzanne.Schwartz@fda.hhs.gov
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.
FYI. Please find attached a table from UCSF-Stanford CERSI of the list of laboratories in the Bay Area that are working on COVID-19 related research. I am also including the link for this table in case you are able to open it. I was not. http://cend.globalhealth.berkeley.edu/2020/03/16/3936/

If you would like to connect with any of these investigators, you can reach out to them directly or you can contact Lawrence Lin at Lawrence.Lin@ucsf.edu (copied on this email) if you need assistance.

Thanks.

Audrey Thomas

More info on Mayo Clinic’s new COVID-19 diagnostic test:

Mayo Clinic Launches COVID-19 Test; Results Within 24 Hours

- 13 Mar 2020
- NEWS
Executive Summary

Mayo Clinic is developing a test to detect COVID-19 in the US.

The Mayo Clinic said it developed a test that can detect the SARS-CoV-2 virus, which causes COVID-19, in various clinical samples. It is the latest in a growing arsenal of test developers in the US to help combat the spread of the disease.

On 12 March, the Mayo Clinic in Rochester, MN announced it developed a real-time polymerase chain reaction (PCR) test that can detect the novel coronavirus in specimens such as nasopharyngeal swabs, sputum, throat swabs, bronchoalveolar lavages and bronchial washings. Results are available within 24 hours, the Mayo Clinic reported.

The test has already been made available to health care providers. All positive samples will be sent to the Minnesota Department of Health or the Centers for Disease Control and Prevention for appropriate follow-up testing and confirmation. The test results will be communicated with public health officials.

"This test should help ease some of the burden that is currently being felt at the Centers for Disease Control and Prevention (CDC) and state public health laboratories," said William Morice II, president of Mayo Clinic Laboratories, which is the global reference laboratory of Mayo Clinic. "We are doing everything we can to help relieve the burden during this time to provide answers for patients here in Rochester and around the world."

Sharon Theimer, a spokesperson for the Mayo Clinic, said that the clinic can provide 200 to 300 tests per day. She anticipates "that the demand will exceed capacity and will be ramping up as soon as new equipment arrives."

On 11 March, the Mayo Clinic also started a "drive-through" process in Rochester to test patients who were directed to the location by the clinic after they have been screened by phone. Theimer could not provide details on how many patients have been tested at the location thus far.

The large hospital-affiliated reference lab is joining the ranks of some of the biggest diagnostic companies – NeuMoDx Molecular Inc., Qiagen NV, Quest Diagnostics Inc. and Laboratory Corp. of America Holdings – that also started providing health care providers with tests to detect COVID-19.

An $8.3bn "Coronavirus Preparedness and Response Supplemental" funding act, approved by US Congress last week and signed into law on 6 March seeks to assist state and local health departments in fighting the spread of the virus. Under the supplemental funding bill, the US Food and Drug Administration will receive $61m to prevent, prepare for and respond to the coronavirus. (Also see "$8.3Bn Coronavirus Response Act Lays Out US FDA’s, CDC’s And Localities’ Roles In Fighting Virus" - Medtech Insight, 10 Mar, 2020.)

Testing Capacity Challenges

Despite ongoing efforts by companies and federal and state agencies to develop tests, the capacity to test people for the illness remains one of the biggest challenges in the US, and testing capacity varies widely across the
country. (Also see "US CMS Providing Medicaid Coverage For COVID-19 Tests, But Congressman Still Sees Gaps For Testing Working Poor" - Medtech Insight, 9 Mar, 2020.)

According to the CDC, as of 12 March there are 1,215 total cases of confirmed coronavirus cases in the US; and 36 reported deaths, reflecting the number of people tested at CDC's laboratory. The Covid Tracking Project, which combines efforts by the Related Sciences, a Denver-based venture creation firm, and journalists by The Atlantic, created a chart to update daily testing capacity for the coronavirus in all US states.

From: Thomas, Audrey A
Sent: Saturday, March 14, 2020 7:03 AM
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <Christine.S.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>
Subject: RE: COVID19

FYI. Please find attached a one-pager from Mayo Clinic CERSI on Mayo’s resources related to COVID-19. If you would like to connect with Mayo Clinic, please contact Nilay Shah at shah.nilay@mayo.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A
Sent: Monday, March 09, 2020 3:51 PM
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <Christine.S.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; joseph.ross@yale.edu; shah.nilay@mayo.edu; Ritchie, Jessica <jessica.ritchie@yale.edu>; Ciaccio, Laura <laura.ciaccio@yale.edu>
Subject: RE: COVID19
FYI. Please find attached a one-pager from Yale University CERSI on Yale’s resources related to COVID-19. If you would like to connect with the Yale University, please contact Joe Ross at joseph.ross@yale.edu (copied on this email).

Thanks.

Audrey Thomas

From: Thomas, Audrey A  
Sent: Sunday, March 08, 2020 7:03 PM  
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Russ B Altman <Russ.Altman@stanford.edu>; 'Giacomini, Kathy' (Kathy.Giacomini@ucsf.edu) <Kathy.Giacomini@ucsf.edu>; 'Lin, Lawrence' (Lawrence.Lin@ucsf.edu) <Lawrence.Lin@ucsf.edu>; Maria.Friciello@ucsf.edu <Maria.Friciello@ucsf.edu>  
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; William Bentley <bentley@umd.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>  
Subject: RE: COVID19

FYI. Russ Altman reached out to me to say that Stanford is in the middle of a crisis. They have a faculty member at the Med School that has tested positive for coronavirus. The school is moving to online classes along with other restrictions. I told Russ not to worry about my request.

I think that this will become more and more prevalent.

Audrey

From: Thomas, Audrey A  
Sent: Sunday, March 08, 2020 11:59 AM  
To: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Russ B Altman <Russ.Altman@stanford.edu>; 'Giacomini, Kathy' (Kathy.Giacomini@ucsf.edu) <Kathy.Giacomini@ucsf.edu>; 'Lin, Lawrence' (Lawrence.Lin@ucsf.edu) <Lawrence.Lin@ucsf.edu>; Maria.Friciello@ucsf.edu <Maria.Friciello@ucsf.edu>  
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; 'jpolli@rx.umaryland.edu' <jpolli@rx.umaryland.edu>; William Bentley <bentley@umd.edu>; 'aanonsen@umd.edu' <aanonsen@umd.edu>  
Subject: RE: COVID19
As requested, I have reached out to the CERSIs for information on their resources related to COVID-19. I just received a one-pager from the University of Maryland CERSI, Baltimore Campus. If you would like to connect with the University of Maryland, please contact James Polli at jpolli@rx.umd.edu (copied on this email).

Thanks.

Audrey Thomas

From: Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>  
Sent: Sunday, March 08, 2020 9:17 AM  
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Aaraojo, Richardae <Richardae.Aaraojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>  
Subject: RE: COVID19

Many thanks Audrey.

I shared with our CoV coordinator in CBER and we both think it would be great if you could reach out to each of the CERSIs with a similar request. Can’t hurt to be more aware of all potentials out there.

Also, I’m assuming you are sharing the information with OCET as well.

Carolyn

From: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>  
Sent: Sunday, March 8, 2020 7:25 AM  
To: Barratt, Ruth <Ruth.Barratt@fda.hhs.gov>; Wilson, Carolyn <Carolyn.Wilson@fda.hhs.gov>; Mendrick, Donna <Donna.Mendrick@fda.hhs.gov>; Kwan, Jonathan <Jonathan.Kwan@fda.hhs.gov>; Braunstein, Emily <Emily.Braunstein@fda.hhs.gov>; Nugent, Bridget <Bridget.Nugent@fda.hhs.gov>; Ruiz, Juan <Juan.Ruiz@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Patterson, Tucker <Tucker.Patterson@fda.hhs.gov>; Bright, Rosalie A. <Rosalie.Bright@fda.hhs.gov>; Patel, Keyur <Keyur.Patel@fda.hhs.gov>; Schneider, Julie <Julie.Schneider@fda.hhs.gov>; Vasisht, Kaveeta <Kaveeta.Vasisht@fda.hhs.gov>; Lee, Christine (OC) <ChristineS.Lee@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Aaraojo, Richardae <Richardae.Aaraojo@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Cc: Blumkemelor, Donna <Donna.Blumkemelor@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Zinn, Rebekah <Rebekah.Zinn@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Smith, Tara (CDRH) <Tara.Smith@fda.hhs.gov>; Margerrison, Edward <Edward.Margerrison@fda.hhs.gov>; Caleb Alexander <galexan9@jhmi.edu>  
Subject: FW: COVID19  
Importance: High
FYI. As per discussion at Thursday's Johns Hopkins University (JHU) CERSI Semi-Annual Update Meeting, Caleb Alexander has prepared a one pager with information on JHU’s resources related to COVID19. CDRH is already connecting with JHU and I wanted to provide you with this information in case any other Center or Office would like to connect with JHU. You can reach out to Caleb, who is copied on this email. Thanks.

Audrey Thomas, M.S.
Center of Excellence in Regulatory Science and Innovation (CERSI) Program Team Leader
UCSF-Stanford CERSI Program Official (PO)
Office of Regulatory Science and Innovation (ORSI)
Office of the Chief Scientist
Office of the Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 1, Rm 4220
Silver Spring, MD 20903
301-796-3520

From: Caleb Alexander <galexan9@jhmi.edu>
Sent: Saturday, March 07, 2020 8:46 PM
To: Thomas, Audrey A <Audrey.Thomas@fda.hhs.gov>; Chada, Kinnera <Kinnera.Chada@fda.hhs.gov>; Saha, Anindita <Anindita.Saha@fda.hhs.gov>; Margerrison, Edward <Edw ard.M a r gerrison@fda.hhs.gov>
Cc: Richard Rothman <rrothma1@jhmi.edu>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>
Subject: COVID19
Importance: High

Hello Colleagues,

Here is a one pager describing some Johns Hopkins’ resources that may be relevant to FDA’s COVID19 response, especially our NIAID-funded Center of Excellence for Influenza Research and Surveillance (CEIRS).

Given the urgency and potential impact of any such collaboration, I have cc’d Richard Rothman, one of the leaders of our CEIRS, as well as Timothy Stenzel, who as you know directs CDRH’s Office of In Vitro Diagnostics and Radiologic Health. We would be happy to touch base early next week, or at any time, to discuss these matters further.

As I note in the memo, we are committed to leveraging the JH-CERSI in any way possible so as to support the FDA’s response to these exceptional circumstances.

Thanks and best regards,
Caleb

G. Caleb Alexander, MD, MS
Johns Hopkins Bloomberg School of Public Health
Center for Drug Safety and Effectiveness
615 N. Wolfe Street, W6035
Phone: (410) 955-8168
Email: galexand@jhsph.edu
From: Michael Brzica <Michael.Brzica@tevapharm.com>
Sent: Friday, March 20, 2020 10:28 AM
To: Schiller, Lowell <Lowell.Schiller@fda.hhs.gov>
Subject: Teva in the Fight Against COVID-19

Lowell:

I just wanted to make sure you [saw the news] that Teva is donating 6 million doses of hydroxychloroquine, a therapy used to treat malaria but has also shown some positive results when used off-label to treat COVID-19. I know FDA is considering adding COVID-19 as an acceptable indication when the science determines it’s appropriate. We’re ramping up production and anticipate having an additional 10 million doses in the channel within 30 days. And just to underscore this, Teva is providing this medicine at no cost to our buyers.

Teva is proud to play a critical role ensuring the nation’s public health. In addition to hydroxychloroquine, Teva manufactures more than 500 medicines in 2,000 different dosage forms and strengths. In fact, Teva provides more than 10% of the nation’s drug supply, providing American patients with approximately 1 out of 7 prescriptions they take. We manufacture these essential medicines in state-of-the-art manufacturing facilities across the country where we employ approximately 7,000 Americans.

Teva is committed to partnering with you as we work through these challenging times. And as we encounter issues and challenges on our own, I may be coming back to you with specific requests for help to ensure we can continue to do the critical work Teva is engaged in on behalf of the nation’s health. If there’s anything I can do for you in the meantime, please don’t hesitate to let me know.

Stay well,

Michael.
See attached.

Thanks!!

-----Original Appointment-----
From: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Sent: Thursday, March 19, 2020 5:49 PM
To: Pennington, Caitlin; Aguilar, Paul; Black, Jennifer; Gross, Karas; Hodnette, Jonathan; Lockheed, Matthew; Paulos, Lauren; Rath, Prakash (FDA); Schipper, Jodi; Tantillo, Andrew; Hinton, Denise; Raghuvanshi, Rakesh; Zembower, Jenna; Patel, Chaitali; 2019-nCoV FDA IMG Planning; Colonius, Tristan; Price, William; Feingold, Daniel; Luebke, Yasemin; Klimczak, Katherine
Cc: Aldridge, Megan; Measer, Gregory; Simms, Joshua; Malais, Tanya; Adleberg, Jill; George, Bryan; Lexer, Susan; Howard, Megan; Groat, Blaine *; Burns, Corey; Rosebraugh, Sydney
Subject: Bicameral Hill Staff Briefing - Participant Line
When: Friday, March 20, 2020 2:00 PM-2:45 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Dial-in: 1-888-606-9801( ) (b)(6)
FYI – clean version if you need!

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Friday, March 20, 2020 2:11 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

attached

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, March 20, 2020 2:07 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi Prakash -
Can you please send me a clean version without the various cross outs and edits?
Thanks,
Anand

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Friday, March 20, 2020 12:35 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Apologies for the delay in sending this document. There was a deluge of information and postings yesterday, and we tried to capture and cut down the info. Everything here is OCC cleared and there shouldn’t be any issue you haven’t already seen or addressed. It’s now alphabetized so hopefully easier to sift through.

For today’s call, we received this update below from HHS on the speakers, and most notably the QA portion. Members will be asking questions. Given all the activity in the administration, this doesn’t change our thinking regarding how many questions FDA may receive, which is 2-3 and possibly on therapeutics (chloroquine) and device shortages (swabs). If you have an opportunity, please plug the blood donation issue and the Commissioner and Dr. Marks have been doing yesterday and today.
I'll join you on the speaker line ahead of time, and not sure if folks will want to discuss any issues, but feel free to raise anything on who should answer what. Please let me know if you have a few minutes to talk.

Here is the line-up of briefers for this afternoon:

HHS: ADM Brett Giroir
ASPR:
CDC: Dr. Butler
FDA: Dr. Shah
NIAID: Dr. Andrea Lerner & Dr. Chase Crawford
CMS: Alec Aramanda

Again, the call in information is as follows:

Dial-in: 888-606-9801
Leader code (b)(6)
Participant code (b)(6)

Members will be on the line this week, and we have requested that only Members ask questions during the Q&A. Please plan to join the call 10 minutes early so the operator has ample time to activate all speaker lines. Let me know if you have any questions!

Thank you,

Prakash
202-868-2627

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:40 PM
To: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi Prakash, Sounds great and thanks in advance for the reactive document. I won’t need a prep for tomorrow. I really appreciate your help.

Anand

From: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>
Sent: Thursday, March 19, 2020 2:10 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi Dr. Shah,
We just confirmed again with HHS that only ASPR and Giroir will provide an update tomorrow. We’ll make sure the reactive document we prepare for you will reflect everything that happened/is happening today. We’ll plan to have that document for you tomorrow mid-morning.

Similar to last time, we expect a few FDA questions, with the focus on the domestic inspection issue and therapeutics. We know you’ve been focused on the response for many weeks now, but please let us know if you would like a prep and we can figure that out.

Thanks,
Prakash

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 3:30 PM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Patel, Chaitali <Chaitali.Patel@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Great, thanks everyone

From: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Date: March 18, 2020 at 3:26:59 PM EDT
To: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

Hi All,

Just wanted to follow up and confirm that this Friday’s briefing is confirmed for 2 pm.

HHS has indicated that they would like an update from ADM Giroir’s team and ASPR at the top on testing and PPE before moving in to the Q&A portion.

Thank you!

Caitlin

From: Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:38 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>, Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: Potential Bicameral Hill staff Call for Friday

2-2:30 works, thank you!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, March 18, 2020 9:36 AM
To: Pennington, Caitlin <Caitlin.Pennington@fda.hhs.gov>; Zembower, Jenna <Jenna.Zembower@fda.hhs.gov>
Hi Jenna & Dr. Shah,

We wanted to let you there may be a call on Friday, 3/20, at 2 pm. We are still working to confirm but wanted to provide a heads up. Does Dr. Shah have availability if this call does happen?

Thanks!

Caitlin

Caitlin M. Pennington, MSM
Special Assistant
Office of Legislation
Caitlin.Pennington@fda.hhs.gov
Direct line: 301-796-7064

U.S. FOOD & DRUG ADMINISTRATION
From: Malais, Tanya [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F13699D67E9C491EAB11150A04F7FC6C-TANYA.MALAI]
Sent: 3/20/2020 5:55:41 PM
To: Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feeca0be694803be6030e97c7b4adb-HINTON]; Mair, Michael [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: 3-20-20 COVID-19 AEG Meeting Notes
Attachments: 3-20-20 COVID-19 AEG Meeting Notes.odt

Good evening,

Attached are my notes from the 3/20/20 AEG meeting.

Tanya E. Malais
Planning Section Chief
2019 Novel Coronavirus (nCoV) IMG
Office: 949-608-2984
Mobile: (b)(9)
Planning Section Email: (b)(6)
24 hour Emergency Number: 1-866-300-4374

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and it should not be disseminated, distributed or copied to persons not authorized to receive such information. If you are not the intended recipient, any dissemination, distribution or copying is strictly prohibited. If you believe you have received this e-mail message in error, please e-mail the sender immediately at Tanya.Malais@fda.hhs.gov.
Dear Tracy,

Thank you for sending for review. I have no questions or concerns with the updated approach.

Best,

RADM Hinton

---

From: MacGill, Tracy <Tracy.MacGill@fda.hhs.gov>
Sent: Friday, March 20, 2020 8:30 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Jones, Estella <Estella.Jones@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Millburne, Kenneth <Kenneth.Millburne@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>; Raguwhanshi, Rakesh <Rakesh.Raguwhanshi@fda.hhs.gov>
Subject: FW: PPE email text
Importance: High

As discussed this week, we’ve had a number of requests for the final project report for the MCMi BAA project Optimizing Respirator Decontamination to Ensure Supplies for Emergency Preparedness with Applied Research Associates. The two viable options considered, based on input from OCET and ORSI leadership and counsel, were to share the report using a CDA and including a disclaimer on the report or just sharing the report with the disclaimer. The current disclaimer on the attached report states:

“The data provided to you was generated by an FDA contractor. The FDA does not endorse or guarantee the efficacy of any method and/or data or potential applications described in the report. Additionally, the views expressed in this report are those of the authors and do not necessarily represent those of the U.S. Food and Drug Administration nor should they be interpreted as official Agency policy or guidance.”

We decided to utilize the CDA and provided it to the four who had requested the report as of yesterday. Two were willing to use the CDA and two haven’t responded. One of those (a physician), raised concerns about potential delays in getting the information to others by not allowing a recipient to share outside their institution and from a potential backlog in processing requests at FDA as the number of requests increase (we are seeing less time between requests).
(b)(5)

Please let me know if you have questions or concerns with the updated approach.

Best,

Tracy
From: Mair, Michael
Sent: 3/21/2020 9:11:49 PM
To: Hinton, Denise
Subject: RE: for IMMEDIATE review: ventilator PR

nope

From: Hinton, Denise
Sent: Saturday, March 21, 2020 8:52 PM
To: Mair, Michael
Subject: FW: for IMMEDIATE review: ventilator PR

See this one?

From: Caccamo, Stephanie
Sent: Saturday, March 21, 2020 6:09 PM
To: CDRH COVID19 Leadership Team; OCCRequests-COVID19; Mednick, David; Gibney, Jaycie; Dennis, Claire; Roth, Lauren; Krueger, Angela C; 2019-nCoV FDA IMG JIC; Anderson, Erika; Hinton, Denise; Lenihan, Keagan
Subject: for IMMEDIATE review: ventilator PR

Hi folks—
Major revisions to the ventilator PR going today, I appreciate your urgent review in next hour.

Please help me in keeping this PR as lay person friendly as possible, while keeping it technically accurate. Thank you.

I appreciate your edits in sharepoint, but I’m copying whole PR below for awareness.


(b)(5)
Hi Stephanie – please add Michal Mair for awareness.

Thank you,

Denise

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, March 21, 2020 6:09 PM
To: CDRH COVID19 Leadership Team <CDRHCOVID19@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Mednick, David <David.Mednick@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Roth, Lauren <Lauren.Roth@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; 2019-nCoV FDA IMG JIC <2019-nCoVFDAIMGJIC@fda.hhs.gov>
Cc: Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: for IMMEDIATE review: ventilator PR

Hi folks—

Major revisions to the ventilator PR going today, I appreciate your urgent review in next hour.

OF NOTE:

Please help me in keeping this PR as lay person friendly as possible, while keeping it technically accurate. Thank you.

I appreciate your edits in sharepoint, but I’m copying whole PR below for awareness.

(b)(5)
Now I’m left off too - life’s too short! Happy Sunday!

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Date: March 22, 2020 at 7:50:45 AM EDT
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: Information for WHTF March 22.docx

Attached.

From: McWilliams, Carly
Sent: Sunday, March 22, 2020 7:44 AM
To: Lenihan, Keagan (Keagan.Lenihan@fda.hhs.gov) <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Information for WHTF March 22.docx

Good Morning,

Attached is information for the TF meeting today. Includes info on ventilator guidance and chloroquine supply. CCI is in red

Thanks,

Carly
I understand why I am not included (not senior leadership worthy) and have given up trying. But u might endeavor to keep yourself in the loop.

---

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Sunday, March 22, 2020 7:44 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Rom, Colin <Colin.Rom@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Subject: Information for WHTF March 22.docx

Good Morning,

Attached is information for the TF meeting today. Includes info on ventilator guidance and chloroquine supply. CCI is in red

Thanks,

Carly
Thanks Michael.

Denise – just for your awareness. The tweet below has been raised within context of the fraudulent products group.

More broadly, I suppose “...be put in use IMMEDIATELY” could be taken to mean under an appropriately designed clinical trial - however I don’t know whether there have been any conversations within leadership regarding providing additional context for this tweet.

This study is mentioned in the Information for Clinicians on Therapeutic Options for COVID-19 Patients just posted on CDC website.

“One small study reported that hydroxychloroquine alone or in combination with azithromycin reduced detection of SARS-CoV-2 RNA in upper respiratory tract specimens compared with a non-randomized control group but did not assess clinical benefit [7]. Hydroxychloroquine and azithromycin are associated with QT prolongation and caution is advised when considering these drugs in patients with chronic medical conditions (e.g. renal failure, hepatic disease) or who are receiving medications that might interact to cause arrhythmias.”

Hi all,

This tweet was posted this morning. I wanted to make you aware, in case this turns into the same issue we had with chloroquine. Right now I don’t see azithromycin available on eBay or Amazon, but this might change quickly and we could see azithromycin for fish and/or birds popping up. I do see it for sale on other smaller shop internet storefronts for birds and fish, but prices have not spiked yet.

Seeking input on whether we want to be proactive and have ORA Health Fraud (Jason Humbert) request that Amazon and eBay be aware of this and create filters and/or monitor.
There are no FDA-approved animal products containing azithromycin
Azithromycin is not an Indexed drug
FDA-approved azithromycin for humans is a prescription drug

HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine. The FDA has moved mountains - Thank You! Hopefully they will BOTH (H works better with A, International Journal of Antimicrobial Agents).....

10:13 AM · Mar 21, 2020 · Twitter for iPhone

33K Retweets 108.1K Likes
Hi all,

What happened with chloroquine is now happening with azithromycin. This appears to be out CVM’s hands now, and I believe may be more appropriate for CDER. I will discontinue including CVM leadership on these e-mails unless told otherwise. I have not yet found price increases on azithromycin labeled for birds and fish.

These are shipping internationally with conversions to the US dollar on the listing, and are on U.S. ebay.

Hi all,

This tweet was posted this morning. I wanted to make you aware, in case this turns into the same issue we had with chloroquine. Right now I don’t see azithromycin available on eBay or Amazon, but this might change quickly and we could see azithromycin for fish and/or birds popping up. I do see it for sale on other smaller shop internet storefronts for birds and fish, but prices have not spiked yet.

Seeking input on whether we want to be proactive and have ORA Health Fraud (Jason Humbert) request that Amazon and eBay be aware of this and create filters and/or monitor.

- There are no FDA-approved animal products containing azithromycin
- Azithromycin is not an Indexed drug
- FDA-approved azithromycin for humans is a prescription drug

Diana
HYDROXYCHLOROQUINE & AZITHROMYCIN, taken together, have a real chance to be one of the biggest game changers in the history of medicine. The FDA has moved mountains - Thank You! Hopefully they will BOTH (H works better with A, International Journal of Antimicrobial Agents).....
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Sunday, March 22, 2020 10:31 PM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>; Abernethy, Amy <Amy.Abernethy@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: WHTF meeting background 3/23

Please see attached.
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE030E97C7B4ADB-HINTOND]
Sent: 3/23/2020 8:17:46 AM
To: Lenihan, Keagan [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bdf521b0105d17d2-Keagan.Leni]
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

Okay – will shore up with Janice – thank you

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 8:17 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Re: Update 1.2: Schedule for Monday, March 23rd

Whatever works with schedule. 11:30 is great.

Sent from my iPhone

On Mar 23, 2020, at 8:10 AM, Hinton, Denise <Denise.Hinton@fda.hhs.gov> wrote:

Janice asked for 1130 so would you like 1100 or 1130?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Monday, March 23, 2020 7:24 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Fwd: Update 1.2: Schedule for Monday, March 23rd

Task force is at 4pm today. So 11 am AEG?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: March 23, 2020 at 6:46:32 AM EDT
To: "Olivarria, Frank" <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Update 1.2: Schedule for Monday, March 23rd

Or also move AEG to 11 and we can do the media prep from 12 to 1:30?
Thanks

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Date: March 22, 2020 at 10:49:45 PM EDT
To: Hahn, Stephen <SH1@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>, Shah, Anand
2020.03.23 Background from WH TF Meeting has been updated since the 10:39 PM message:

Denise: one edit re: ventilator guidance, below:

- **Ventilator supply strategies for HCPs guidance**
  FDA will issued an immediately in effect guidance on March 22 to provide a policy for expanding the availability of ventilators and accessories as well as other respiratory devices during the COVID-19 pandemic.

Attached (updated doc).

---

Your first call is scheduled for 7:10 AM: **Quick Touch Point: Media**[Stephanie Caccamo will call your cell] (your first in-person will be at 10:30 AM at HHS, you will be at HHS until 2 PM, when you depart for the WH, and you will return back to HHS by 7:50 PM for Remote Media Interview with Tucker Carson [from the HHS Studio])

**7:10-7:15 am Quick Touch Point: Media**
Note: Materials attached. POC: Stephanie Caccamo will call you (her number is:(_(b)(6)___)

**7:15-7:30 am Telecon: Radio Interview - Boston radio: The Kuhner show**
Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: Brittney Jennings: (_(b)(6)___) NLT 7:15 AM

**7:30-7:45 am Telecon: Radio Interview - Steve Gruber Show, Flint, Michigan**
Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: Ivey: (_(b)(6)___) NLT 7:30 AM

**7:45-7:55 am Telecon: Radio Interview - Bloomdaddy (David), Pittsburgh, Host: BLOOMDADDY (DAVID)**
Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. You are to call: (_(b)(6)___) (back up just in case): (_(b)(6)___) NLT 7:45 AM

**8:00-8:30 am TELECON ONLY: Commissioner’s Daily Check-In**
Note: Dial-In (1-877-465-7975, (_(b)(6)___)

10:00 am Uber to HHS

10:30-12:00 pm Media Prep: Tucker Carlson Interview
Note: Location – HHS Studio (pending confirmation from Laura, otherwise will be in FDA Suite). Materials attached, same as 7:10 AM: Quick Touch Point: Media call.

10:00-12:00 pm HOLD: White House Buffer

12:00-1:00 pm COVID-19 AED Meeting
Note: Dial-In (1-877-465-7975,, (b)(6)#)

2:00 pm Travel to WH

2:00-2:30 pm Telecon: Weekly CFSAN Meeting with the Commissioner
Note: Agenda attached. Dial-In (1-877-465-7975,, (b)(6)#). You will take this call en route to the WH, however we are attempting to move the call up to 1:15 PM to avoid you having to take this en route – will text you and Colin if this changes.

2:30-3:00 pm Clear White House Security

3:00-3:30 pm Telecon: Senator Richard Durbin and Commissioner Hahn
Note: You will take this call at the WH, so avoid taking it en route to the WH. Materials attached, additional TP’s on COVID-19 forthcoming. Dial-In (1-888-913-9943,, (b)(6)#).

3:30-4:00 pm Telecon: Bi-Weekly Check-In: AAbernethy / Dr. Hahn

3:50 pm Walk to WHSR for WHTF Meeting

4:00-5:00 pm White House Coronavirus Task Force Meeting
Note: Agenda and seating chart forthcoming. Janice will forward once received.

5:00 pm Travel to TBD (HHS or Residence)

6:00-6:30 pm Daily Check-In
Note: Dial-In (1-877-465-7975)

7:15 pm Travel to HHS (from residence, if not already at HHS)

7:45 pm Walk to HHS Studio

8:00-8:30 pm Interview (Remote): Tucker Carlson
Note: Materials attached, same as 7:10 AM: Quick Touch Point: Media call. The interview will be for

Reading Material(s):
1. nCoV Outbreak SITREP: March 22, 2020, attached
2. 2020.03.23 Background from WH TF Meeting, attached

Calendar Snapshot:
<image001.png>
From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/23/2020 3:29:56 PM
To: Tantillo, Andrew [/o=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]
Subject: RE: Question re: FEMA Address

Thank you for your quick response!

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Question re: FEMA Address

Yes – the address is Covidsupplies@fema.dhs.gov and the site is https://www.fema.gov/coronavirus/how-to-help.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:19 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Question re: FEMA Address

Hi Andrew,

Would you please send the final contact reference document you worked on over the weekend? In it, you wrote the legislation fda address would be replaced with the FEMA address. Do you have that address for reference?

Companies seeking to Import, Donate, or Manufacture Medical Products to Aid the U.S. Response to COVID-19: If a constituent company would like to import, donate, or produce medical products to help with the COVID-19 response such as personal protective equipment, swabs, etc., please send these inquiries to legislation@fda.hhs.gov. Please include as many details as possible about the request and contact information for the company, either an agent in the U.S. or the company itself. This information is necessary for us to respond and get you and your constituents the additional information you need.

Thank you,

Denise
But that address is not for donations. I gave that one to him below earlier today. So just wanted to talk for a minute about best approach.

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, March 23, 2020 3:30 PM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: FYSA: Question re: FEMA Address

Hi Andrew,

Would you please send the final contact reference document you worked on over the weekend? In it, you wrote the legislation fda address would be replaced with the FEMA address. Do you have that address for reference?

Companies seeking to Import, Donate, or Manufacture Medical Products to Aid the U.S. Response to COVID-19: If a constituent company would like to import, donate, or produce medical products to help with the COVID-19 response such as personal protective equipment, swabs, etc., please send these inquiries to legislation@fda.hhs.gov. Please include as many details as possible about the request and contact information for the company, either an agent in the U.S. or the company itself. This information is necessary for us to respond and get you and your constituents the additional information you need.

Thank you,

Denise
The Bio Fire EUA is ready for signature.
Michael will no longer be clearing the IVD ones, so it’s good to go from OCET. Thanks, Liz

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
Dear NIH Family:

From: Johanson, Elaine [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=636A76A574AB4D4498438B47493217BC-JOHANSONE]
Sent: 3/25/2020 2:41:45 PM
To: Hinton, Denise [O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=85feeca0be0694803be6030e97c7b4adb-HINTOND]; Raghuwanshi, Rakesh
[O=ExchangeLabs/ou=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=3084aedbc6049edabcb11776f265a2a-Rakesh.Ragh]
Subject: FW: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID
Remdesivir Trial

Elaine Johanson
Director, Office of Health Informatics (Acting)
Office of the Chief Scientist
Office of Health Informatics
U.S. Food and Drug Administration
Tel: 301-796-7315
elaine.johanson@fda.hhs.gov

From: Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 1:52 PM
To: OHI <OHl@fda.hhs.gov>
Subject: Fyi: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID
Remdesivir Trial

From: Lewandoski, Mark (NIH/NCI) [E] <lewandom@mail.nih.gov>
Sent: Wednesday, March 25, 2020 1:12 PM
To: Bright, Roselie A. <Roselie.Bright@fda.hhs.gov>
Subject: FW: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID
Remdesivir Trial

From: NIH Executive Secretariat
Date: Wednesday, March 25, 2020 at 1:10 PM
To: List NIH-ALL-STAFF
Subject: Message from the Director: CORONAVIRUS UPDATE - Clinical Center Enrolls First Participants in NIAID
Remdesivir Trial
Resent-From:
Last night the NIH Clinical Center enrolled its first two research participants with COVID-19 as part of the National Institute of Allergy and Infectious Diseases (NIAID) randomized, controlled clinical trial of the antiviral remdesivir. The patients were transported from Suburban Hospital and placed in the Special Clinical Studies Unit (SCSU), a highly specialized infectious disease containment and treatment facility within the hospital. This facility was successfully used from 2014 to 2016 to care for patients with Ebola Virus Disease and is used for many other infectious disease trials. This is yet another way that NIH is playing a critical role in addressing the challenge of COVID-19.

The NIH Clinical Center is specially equipped to handle patients with highly infectious diseases, including high-level respiratory isolation capabilities and highly trained infectious diseases and critical care specialists. These staff have been prepared to receive research participants and have implemented strict infection control practices optimized to prevent spread of potentially transmissible agents such as the novel coronavirus from an infected patient either to health care personnel or to the surrounding hospital environment.

NIAID announced the launch of the trial on February 21, 2020, at the University of Nebraska Medical Center in Omaha. Since then more than 37 study locations have been added, including the NIH Clinical Center. The trial is evaluating the safety and efficacy of remdesivir in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement, including abnormal sounds heard through the stethoscope when breathing (rales) with a need for supplemental oxygen, abnormal chest X-rays, or inadequate oxygenation requiring mechanical ventilation. Individuals with confirmed infection who have mild, cold-like symptoms or no apparent symptoms will not be included in the study. The trial sites are enrolling participants quickly and we are hopeful that an answer on safety and effectiveness will be reached this spring.

I think we’re all anxious for the development of safe and effective vaccines and treatments for this highly infectious strain of coronavirus. Currently, however, mitigation and containment remain our best options for reducing community spread of the infection. I want to thank you for your support of the physical distancing measures that have been put in place at NIH. I know it’s not easy, but we will get through this together.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director, NIH
Thanks for sharing, Alice!

Alice
Office (301) 796-8449
Mobile (b)(6)
Fax (301) 847-3539

Notice: This message, together with any attachments, contains information that may be confidential, proprietary and/or legally privileged and is intended solely for the use of the individual or entity named above. If you are not the intended recipient, you are hereby notified that any use, dissemination, distribution, or copying of this message or its content is strictly prohibited. If you have received this message in error, please notify sender immediately and delete the message without making a copy. Thank you.

Dear NIH Family:

Last night the NIH Clinical Center enrolled its first two research participants with COVID-19 as part of the National Institute of Allergy and Infectious Diseases (NIAID) randomized, controlled clinical trial of the antiviral remdesivir. The patients were transported from Suburban Hospital and placed in the Special Clinical Studies Unit (SCSU), a highly

FDA-OSJI-FOIA-2020-3541_00006980
specialized infectious disease containment and treatment facility within the hospital. This facility was successfully used from 2014 to 2016 to care for patients with Ebola Virus Disease and is used for many other infectious disease trials. This is yet another way that NIH is playing a critical role in addressing the challenge of COVID-19.

The NIH Clinical Center is specially equipped to handle patients with highly infectious diseases, including high-level respiratory isolation capabilities and highly trained infectious diseases and critical care specialists. These staff have been prepared to receive research participants and have implemented strict infection control practices optimized to prevent spread of potentially transmissible agents such as the novel coronavirus from an infected patient either to health care personnel or to the surrounding hospital environment.

NIAID announced the launch of the trial on February 21, 2020, at the University of Nebraska Medical Center in Omaha. Since then more than 37 study locations have been added, including the NIH Clinical Center. The trial is evaluating the safety and efficacy of remdesivir in hospitalized adults with laboratory-confirmed SARS-CoV-2 infection and evidence of lung involvement, including abnormal sounds heard through the stethoscope when breathing (rales) with a need for supplemental oxygen, abnormal chest X-rays, or inadequate oxygenation requiring mechanical ventilation. Individuals with confirmed infection who have mild, cold-like symptoms or no apparent symptoms will not be included in the study. The trial sites are enrolling participants quickly and we are hopeful that an answer on safety and effectiveness will be reached this spring.

I think we’re all anxious for the development of safe and effective vaccines and treatments for this highly infectious strain of coronavirus. Currently, however, mitigation and containment remain our best options for reducing community spread of the infection. I want to thank you for your support of the physical distancing measures that have been put in place at NIH. I know it’s not easy, but we will get through this together.

Sincerely yours,

Francis S. Collins, M.D., Ph.D.
Director, NIH
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 3/26/2020 10:12:47 AM
To: Fortney, Russell [O=Exchangelabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86db918272164d9ea5d88d0dc8721f10-FORTNEYR]
Subject: RE: WSJ on Safe and Effective

Thanks

From: Fortney, Russell <Russell.Fortney@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:19 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FYI: WSJ on Safe and Effective

FDA Shouldn’t Keep Safe Drugs off the Market
Congress’s mandate that medications be proved effective is unnecessary and delays potential cures.

By Charles L. Hooper and David R. Henderson
March 25, 2020 6:28 pm ET

A laboratory technician prepares Covid-19 patient samples for testing in Lake Success, N.Y., March 11.

The federal government requires pharmaceutical companies to prove that their drugs are both safe and effective before putting them on the market. Before 1962, companies needed to prove only safety. While there is some appeal to this two-hurdle approach, evidence suggests that there is only a slight benefit and a tremendous cost. With the Covid-19 pandemic sweeping the world, there has never been a better time to revoke the Food and Drug Administration’s efficacy requirement.

The thinking behind the FDA’s two-hurdle approach is that ineffective drugs cost money and impose an opportunity cost: While the ineffective drug is being used, potentially effective ones are not. But researchers who have studied the 1962 law, known as the Kefauver-Harris Amendments, have concluded that before it was enacted, ineffective drugs were a small percentage of the market and therefore not much of a problem. Further, the Kefauver-Harris Amendments dramatically increased the time and cost of getting new drugs approved. Evidence provided by University of Chicago economist Sam Peltzman suggests that the number of new drugs approved dropped by 60% in the decade following the law change. We have fewer ineffective drugs, but also far fewer effective ones than we could have had.

That’s not all that’s wrong with the Kefauver-Harris Amendments.

Before 1962, patients and doctors needed to try drugs to see if they worked for a particular patient at a particular time. It’s called trial and error and, despite the change in law, is still the standard medical approach.
To understand how little the FDA’s two-hurdle approach contributes, consider Merck’s Keytruda (pembrolizumab), which has recently become one of the hottest drugs on the market. Keytruda got some good press after Jimmy Carter, who was suffering from melanoma, was diagnosed as cancer-free after taking it. Mr. Carter was lucky because in one clinical trial Keytruda destroyed or reduced the tumors in only 34% of patients. Keytruda—which was the fourth biggest-selling drug globally in 2018 and brought in worldwide revenues of $11.1 billion last year—is far from a sure thing.

Does the FDA, which approved Keytruda as safe and effective for melanoma, know which patients will benefit from it? No. The potential benefits described on the drug’s label are what happened to strangers in another time and place. Patients still have to try Keytruda to know if it will help them. An FDA approval for efficacy is largely duplicative.

Enter Covid-19, the disease caused by the new coronavirus, SARS-CoV-2. There are no proven therapies to treat an infection of that virus. One of the most promising candidates is Gilead Sciences’ remdesivir, which has shown some potential in treating other coronaviruses, such as SARS and MERS. Due to its use in treating Ebola infections, remdesivir is known to be generally safe.

With the FDA’s two-hurdle requirement in place, however, remdesivir must be proven effective in clinical trials before it can be sold for widespread use in Covid-19. These clinical trials take time, and they still won’t answer many of the questions doctors have about the drug’s use against Covid-19 now. What’s the right dose to get remdesivir into the lungs? How early should it be given? If it is given to sick patients already on ventilators in hospitals, will it help? All these things will depend on the individual patient.

And then, even if remdesivir is approved by the FDA, patients and doctors will still resort to trial and error, because the success rate won’t be 100%.

Instead, the FDA should allow patients and doctors to try remdesivir today. We know it’s safe, and there are no other proven therapies. With more widespread usage, the medical community will have a tool to fight back against Covid-19. Controlled clinical trials can continue largely as they normally would. Though access to an experimental therapy won’t be an incentive to join a clinical trial, many others remain—such as excellent free care and a sense of pride in helping society and other patients. This two-pronged approach would not only potentially save thousands of lives but also provide much more information.

If you were diagnosed with Covid-19 today, would you choose to take nothing? Or would you want a safe drug that has shown some potential against the virus? We suspect the great majority of Covid-19 patients would choose the latter option. And they would get it today, not months from now, when it would be of no use to them.

This same process plays out every day with other conditions that can be more dangerous than Covid-19. While patients and doctors continue to resort to trial and error out of necessity, the government insists that they initiate their experiments only after the FDA has completed its. This is a critically flawed approach to medicine.

Even as the pandemic robs Americans of their jobs, health and lives, it could reward us with a silver lining if we use the opportunity to take a hard look at our drug-approval process. Revoke the FDA’s drug-efficacy requirement.

Mr. Hooper is president of Objective Insights Inc., a company that consults for life-science companies. Mr. Henderson, a research fellow with the Hoover Institution, was senior health economist with President Reagan’s Council of Economic Advisers.
Thanks Janet, Keagan, and Stacy. If agreed, Liz Sadove can work with Jacqueline

I believe Jaqueline is leading, correct Janet? Can we filter things to her, or do you want another lead?

I have reached out to Rick Bright and we will get organized with him.

I cannot emphasize enough that we need someone to lead this project and Jeet has contact info for everyone at ASPR, CDC, and BARDA working on this.

Do we have anyone to ask at CDC?
From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:29 AM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eu

Just to clarify, (b)(5)

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:21 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eu

Hi

(b)(5)

Thanks
Jacqueline

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Thursday, March 26, 2020 8:15 AM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:21 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eua

That is helpful.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:21 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eua

Fyi, Stacy sent an email to a broader group with HHS and ASPR/BARDA to confirm that!

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: RE: chloroquine eua

Fyi, Stacy sent an email to a broader group with HHS and ASPR/BARDA to confirm that.

I'll keep this group posted on what we hear.

Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 10:00 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: chloroquine eua

(b)(5)
From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 9:56 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Subject: RE: chloroquine euA

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 9:28 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: chloroquine euA

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 8:22 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Franklin, Joseph <Joseph.Franklin@fda.hhs.gov>
Subject: chloroquine euA

Fyi. __________

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 7:50 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Gormley, Nicole <Nicole.Gormley@fda.hhs.gov>; Leissa, Brad G <Brad-Leissa@fda.hhs.gov>
Subject: RE: HHS distribution of HCQ from Pharma Cos.
From: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:57 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Gormley, Nicole <Nicole.Gormley@fda.hhs.gov>; Leissa, Brad G <Brad.Leissa@fda.hhs.gov>
Subject: FW: HHS distribution of HCQ from Pharma Cos.

From: Woodcock, Janet <janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, March 25, 2020 6:56 PM
To: Corrigan-Curay, Jacqueline <Jacqueline.Corrigan-Curay@fda.hhs.gov>
Subject: Fwd: HHS distribution of HCQ from Pharma Cos.

This is what another part of HHS says—see below. Jw

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Date: March 25, 2020 at 6:46:00 PM EDT
To: Hamel, Joseph (OS) <joseph.Hamel@hhs.gov>, Kane, Elleen (OS) <Elleen.Kane@hhs.gov>, ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>
Cc: Guram, Jeet <jeet.Guram@fda.hhs.gov>, Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: HHS distribution of HCQ from Pharma Cos.

+ Janet Woodcock
Patrizia

From: Hamel, Joseph (OS/ASPR/OIA) <joseph.Hamel@hhs.gov>
Date: March 25, 2020 at 6:37:41 PM EDT
To: Kane, Elleen (OS) <Elleen.Kane@hhs.gov>, ASPRMEDIA (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>
Cc: Guram, Jeet <jeet.Guram@fda.hhs.gov>, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Subject: RE: HHS distribution of HCQ from Pharma Cos.

Per Gary’s last note

From: Kane, Elleen (OS/ASPR/OEA) <Elleen.Kane@hhs.gov>
Sent: Wednesday, March 25, 2020 6:35 PM
To: ASPRMedia (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: RE: HHS distribution of HCQ from Pharma Cos.

Joe, checking back on accuracy here. Thanks!

From: Kane, Elleen (OS/ASPR/OEA)
Sent: Wednesday, March 25, 2020 3:32 PM
To: ASPRMedia (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>; Hamel, Joseph (OS/ASPR/IO) <Joseph.Hamel@hhs.gov>
Subject: FW: HHS distribution of HCQ from Pharma Cos.

I talked with Joe Hamel about this. Here’s what I propose as a response.
Joe, can you check accuracy?

Thank you!

Vr, Elleen

From: Marcy O’Koon <mokoon@arthritis.org>
Sent: Wednesday, March 25, 2020 3:21 PM
To: ASPRMedia (OS/ASPR/COO) <ASPRMEDIA@hhs.gov>
Subject: HHS distribution of HCQ from Pharma Cos.

Hi— I am from the Arthritis Foundation national office. We have been keeping our constituents informed as the coronavirus crisis unfolds. A very hot topic right now is the shortage of hydroxychloroquine. I understand that the distribution or allocation (?) of the quantity that Novartis is donating, above its normal production, is being handled by HHS. I would like to talk to someone about that. Are you the right one? If not, can you connect me with someone who can help?

This is an urgent matter for us and have copy live on the website that we are updating, so would appreciate a quick reply (although I understand how crazy-busy you all must be).

Thank you.

Marcy O’Koon
Arthritis Foundation
Senior Advisor, Consumer Health \ Home Office
1335 Peachtree St., NW, Suite 600 | Atlanta, GA 30309
404.965.7616 | mokoon@arthritis.org

FDA-OSJI-FOIA-2020-3541_00006951
Dear Ms. Hinton

Please find attached a letter requesting authorization pursuant to the EUA issued on March 2, 2020 to distribute N95, KN95 and other PPEs to help combat the COVID-19 outbreak in the US. We have attached our credentials as a medical device company and a list of our current providers of masks and potentially other PPEs. In an effort to assure a speedy delivery of the products, we are also proposing to ship directly to the facilities in need. We will keep accurate records of all transactions and have provisions to handle complaints and reports MDRs as required by the EUA.

Thank you for your time and effort in this matter.

Regards,
(b)(6)
Director QA/RA

(b)(4)

(b)(6) (cell)
From: Gump, Robert <Robert.Gump@fda.hhs.gov>
Date: March 28, 2020 at 2:13:53 PM EDT
To: Finnen, April <April.Finnen@fda.hhs.gov>, 2019-nCoV FDA IMG JIC Leadership <2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov>
Cc: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Subject: FW: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients

FYI... shared with our animal programs

(b)(5)

Bob Gump, BS, CMAR
Interdisciplinary Scientist/Biologist
FDA/OC/OCS/OCET

O: 301-796-0205
C:

From: Gump, Robert
Sent: Saturday, March 28, 2020 2:04 PM
To: Dennis, John <John.Dennis@fda.hhs.gov>; Gonzales, Raoul <Raoul.Gonzales@fda.hhs.gov>; Mack, Pamela <Pamela.Mack@fda.hhs.gov>; Tinaza, Constante <Constante.Tinaza@fda.hhs.gov>; Ferrine, Anthony <Anthony.Ferrine@fda.hhs.gov>; Moran, Kellie <Kellie.Moran@fda.hhs.gov>; Evans, Eric <Eric.Evans@fda.hhs.gov>; Reed, Kevin J <Kevin.Reed@fda.hhs.gov>; Prince, Kahrin <Kahrin.Prince@fda.hhs.gov>
Cc: Jones, Estella <Estella.Jones@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>; Skinner, Brianna <Brianna.Skinner@fda.hhs.gov>
Subject: FW: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients

(b)(5)

(see attached email).

Bob Gump, BS, CMAR
Interdisciplinary Scientist/Biologist
FDA/OC/OCS/OCET
From: MacGill, Tracy <Tracy.McGill@fda.hhs.gov>
Sent: Saturday, March 28, 2020 12:36 PM
To: OC OCET STAFF <OCOCETSTAFF@fda.hhs.gov>
Subject: Duke researchers are decontaminating N95 masks so doctors can reuse them to treat coronavirus patients

Here are the package of documents that likely will not be ready for signature for another 2 hours- pieces are going up to Janet Woodcock, etc. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
Signed – thanks for all your endless work on these!

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Saturday, March 28, 2020 11:35 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: final hydroxy/Chloroquine EUA

I’ve pulled out the letter to sign because this one had a lot of attachments. Attached is the entire package. Thanks!

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
Good morning. This is the last version I have in email but is very much in draft. When I receive the clean version – I’ll send to you.

Thanks,
Denise
Good morning. This is the last version I have in email but is very much in draft and is updated as needed. When I receive the clean version – I'll send to you. Let me know if you have any additions for consideration.

Thanks,
Denise
Good morning Jackie. Do you want to send to OCC or have Rakesh track and follow. Anyone else?
Hi Michael,

Please let me know if IMG is handling review and clearance of this. OGCP, OCS (Jackie), and OCC (Denise Zavagno reviewed previously). Not certain if anyone else from OP needs to see it.

Call me if anything else needed.

Thank you,
Denise
Hi. Please let me know if you have any comments/edits. Also please share w/anyone else that should review. Thx - michael

From: Fernandez, Jose (OS/OGA) <Jose.Fernandez@hhs.gov>
Sent: Sunday, March 29, 2020 5:35 PM
To: Marston, Hilary D (NIH) <hilary.marston@nih.gov>; Higgs, Elizabeth S (NIH) <ehiggs@niaid.nih.gov>; Shuy, Bryan (OS) <Bryan.Shuy@hhs.gov>; Moudy, Robin (OS) <Robin.Moudy@hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>
Subject: SHORT FUSE REVIEW: USG International COVID-19 Strategy
Importance: High

Dear Colleagues,

The National Security Council (NSC) requested the development of an overarching framework for U.S. government activities implemented internationally to support countries’ public health responses to the coronavirus (COVID-19) pandemic and to prioritize action to support the U.S. response to COVID-19 globally as we move forward. This strategy will guide U.S. government policy, program, and resource decisions and communicate the U.S. government international public health response to the global crisis. It outlines the U.S. government’s approach to support response to the COVID-19 pandemic abroad, in support of National Security Strategy objectives to protect the American people, homeland, and way of life, preserve peace through strength, and advance American influence. The strategy calls on the expertise of multiple Executive Branch departments and agencies including the Department of State, U.S. Agency for International Development, Department of Health and Human Services, Centers for Disease Control and Prevention, Department of Defense, and others. It is nested under existing White House-level strategies including the National Security Strategy, National Biodefense Strategy, and the Global Health Security Strategy, which already define foundational objectives, roles, and responsibilities for executive branch agencies in protecting U.S. health security by mitigating the spread of infectious disease threats abroad.

Attached is the latest version of the strategy (U.S. Government Action Plan to Support Partner Countries in Responding to COVID-19) that includes edits OGA, along with a shorter external talking points document. Departments and agencies have been asked by NSC to obtain clearance of the attached documents by 10:00 am Monday March 30. OGA has
agreed to compile for HHS, so please provide me with your consolidated agency edits **NLT 9:00am Monday March 30.** Our apologies in advance for the fast turnaround.

Thank you.

Jose

**Jose A. Fernandez, Ph.D.**  
Deputy Director, Office of Pandemics and Emerging Threats  
Switzer Building – Office 2305  
Office of Global Affairs  
U.S. Department of Health and Human Services  
Phone: 202-260-6820 (desk); 202-657-2048 (mobile)  
www.globalhealth.gov
Sorry! I spoke too soon. FDA updated its Clinical Trials COVID-19 guidance, so I added a minor edit to the last page of OHRP’s document to include that.

Thanks!

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Sunday, March 29, 2020 8:19 PM
To: Less, Joanne <Joanne.Less@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>
Cc: Robb, Melissa <Melissa.Robb@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Attachments: Final_OHRP statement on COVID-19 draft 3-20-20 v2 clean.docx

Hi, Denise,

I do not have any additional comments on this document. We shared comments with OHRP on March 18th, and they have addressed those concerns.

Thank you,

Joanne

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:53 PM
To: O'Shaughnessy, Jacqueline A <Jacqueline.OShaughnessy@fda.hhs.gov>; Less, Joanne <Joanne.Less@fda.hhs.gov>
Subject: RE: Action requested: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Hi Jackie and Joanne,

If you haven’t received already, please see the attached document for review and comment.

Thank you,

Best,

Denise

---

From: Russ, Wanda <Wanda.Russ@fda.hhs.gov>
Sent: Saturday, March 28, 2020 7:31 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; COVID-19 IMG <COVID19IMG@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Varnado, Martina <Martina.Varnado@fda.hhs.gov>
Subject: Request for Expedited R/C by the Department - re: COVID-19 Due: 3/30 by Noon
Importance: High

Good morning.

The Department sent the attached document yesterday evening for FDA’s r/c with a due date of Noon on March 30th.

Office for Human Research Protections
Department of Health and Human Services
OHRP Guidance on COVID-19
March 20, 2020

Please have the appropriate folks r/c and provide me with the edits/comments in Track changes.

Let me know if you have any questions/concerns.

Thank you,

Wanda
Good evening Mr. Stevens,

Thank you for your email. I have included the email of the CDRH team to contact you for guidance in follow up to the information you presented below.

Best regards,

Denise

RADM Denise M. Hinton
U.S. Public Health Service
Chief Scientist
Food and Drug Administration
Office (301) 796-4880
Thanks,

Sean Stevens, P.E.
HiLine Engineering & Fabrication, Inc.
2105 Aviator Dr. Richland WA, 99354
sean.stevens@hilineeng.com
509-420-7002 Desk

This email was scanned by Bitdefender
UNCLASSIFIED // FOR OFFICIAL USE ONLY
Good morning,

Attached you will find comments from OCC. I have included Claire Davies who reviewed for legal issues involving devices.

Going forward, and in order to ensure proper tracking, please forward any COVID related documents for OCC’s review to OCC’s COVID inbox: [b](5)@fda.hhs.gov.

Kind regards,
Denise Zavagno
Senior Counsel
Good morning.

Please confirm that this is the only comment FDA has, or are we waiting input from others.

Thank you,

Wanda

Sorry! I spoke too soon. FDA updated its Clinical Trials COVID-19 guidance, so I added a minor edit to the last page of OHRP's document to include that.

Thanks!

Hi, Denise,

I do not have any additional comments on this document. We shared comments with OHRP on March 18th, and they have addressed those concerns.

Thank you,
Hi Jackie and Joanne,

If you haven’t received already, please see the attached document for review and comment.

Thank you,

Best,

Denise

Good morning.

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Office for Human Research Protections
Department of Health and Human Services
OHRP Guidance on COVID-19
March 20, 2020

Please have the appropriate folks r/c and provide me with the edits/comments in Track changes.

Let me know if you have any questions/concerns.

Thank you,

Wanda
From: Hinton, Denise
Sent: Sunday, March 29, 2020 7:20 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: FW: revised battelle eu

Signed – thank you!

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Sunday, March 29, 2020 7:03 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: revised battelle eu

Attached is the revised Battelle EUA. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Monday, March 30, 2020 4:56 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>
Cc: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>
Subject: EUA Products Assignment

Hello all: looping everyone into one email for awareness. I am developing a very high level document of products we have authorized, sponsors and what they do for external stakeholders. I have worked on a high level introduction and the non-diagnostic products. I also included some resources but again, very high level as to not overwhelm.

Toby and Elizabeth are helping on diagnostics. (the version they are working on is separate) – how is it going?

Who from CDER should be reviewing this? Rosemary Roberts?
OCET can you please review this in the mean time? I would appreciate assistance on sharepoint as my computer has basically been treating me like I don’t actually work at FDA or it has a terrible case of COVID19.

Thank you!
Thanks!

---

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, March 30, 2020 6:07 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Qiagen EUA

First EUA of 2 to sign for the night. This is a multiplex EUA. A bit different, but looks good. Thanks!

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
Thanks Liz – much appreciated.

Best,
Denise

---

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Monday, March 30, 2020 6:48 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: 2d EUA for the night- NeuMoDx

NeuMoDx ready for signing. This one was a straight-forward one- high and moderate complexity labs.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTIAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications
- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target this week
- Potential EUA for vaporized hydrogen peroxide, so hospitals may be able to re-sterilize N95s, possibly up to 20 times target ~mid-week

Medical Product Development & Availability

DIAGNOSTICS
- Pre-EUAs: 249 [+14]
- LDTs: 112 [+2] LDT firms have indicated that they have completed validation and will initiate testing
- EUAs:
  - Submissions: 88 [+9] (2 withdrawn [b](4) no data)
  - Amendments: 12 [+2] requests, 5 have been granted; 2 required re-issue of the original EUA

PPE: Authorized an amendment to Battelle’s EUA allowing them to operate their decon system at multiple locations

VENTILATORS: Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

NEW DEVICE GUIDANCE
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease [COVID-19] Public Health Emergency

HUMAN DRUGS: 26 [+2] pre-IND, 8 IND, 0 [-1] Pre-EUA, 1 [-1] EUA request; 1 EUA issued (chloroquine/hydroxychloroquine)
- Remdesivir: 574 EIND requests authorized to date; ACTT trial - 253 (+31) patients enrolled (+40 target) at 37 sites

HAND SANITIZER: CDER/OMQ has been contacting manufacturers that are large producers of hand sanitizer; [b](4) can manufacture a large quantity of hand sanitizer and will partner with the Red Cross; [b](4) are also interested and will consult with OMQ when the API ethanol guidance is released.

BIOLOGICS: 17 [+1] pre-IND, and 1 IND

Inspections
- ORA Inspections: ORA continues to accomplish inspections that are deemed Mission Critical and ORA IMG Reps continue to triage local field inquiries from states, industry, and other agencies into IMG through RFI process.

[1] EUA submissions should be submitted within 15 working days of FDA notification
[2] Resulting from the new Regulatory relief policy update
<table>
<thead>
<tr>
<th>Product</th>
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</thead>
<tbody>
<tr>
<td>Biologics</td>
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<tr>
<td>Human Drugs</td>
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<tr>
<td>N95s</td>
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<tr>
<td>Surgical Masks</td>
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<tr>
<td>Surgical Gowns</td>
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<tr>
<td>Surgical Isolation Gowns</td>
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<tr>
<td>Gloves</td>
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<tr>
<td>Surgical accessories and non-surgical isolation gowns</td>
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<tr>
<td>Infrared Thermometers</td>
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<tr>
<td>Ventilators</td>
</tr>
<tr>
<td>Vent support devices</td>
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<tr>
<td>Essential Devices - INTL[4]</td>
</tr>
<tr>
<td>Animal Drugs</td>
</tr>
</tbody>
</table>

### Fraudulent Products
- **Warning Letters:** 12 [+3] issued; 40 pending
  - 3 issued today: (1) Haloscope Inc., (2) JRB Enterprise Group Inc. DBA Anti-Aging Bed, and (3) FullerlifeC60 LLC

### Food Safety
- Nothing to report

### Legislative Activities
- **Briefings/Hearings Today:** N/A
- **Upcoming Briefings/Hearings:** N/A

### Communications
- **Released today:**
  - Press statements - Coronavirus (COVID-19) Updates:
  - FDA expedites review of diagnostic tests to combat COVID-19
  - FDA on Signing of the COVID-19 Emergency Relief Bill, Including Landmark Over-the-Counter Drug Reform and User Fee Legislation

---

[3] Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

[4] China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain

(b)(5)
Cross-cutting: Updated guidance, Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, with an appendix adding questions and answers

CDRH: Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

Listserv messages/social media on QAs for clinical trials during COVID-19 (updated guidance to add QAs)

Operations

- PHS Deployments: 169 (+8) officers are deployed; 57 (-9) officers are rostered to deploy

Requests for Information (RFIs)[5]

- Total Received: 125 (+10)
- Total Pending: 22 (18%)
- Total Resolved: 103 (+5) (82%)

External Situation Reports

- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 30, 2020

[5] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/30/2020
JIC daily check-in M-F, 9:30 – 10:30 a.m. **WebEx only.** For first ~30 minutes, we will run down status of current items. 10:00-10:30, will focus on forward look/strategy or topic of the day. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

**Reminders:**
- Please put all documents for JIC/IMG & OCC review in the IMG/JIC SharePoint, and route with a SP link (not as file attachment)
  - This is on request of IMG leadership for version control, and to cut down on # of emails
  - Put text for review below the SP link in your email, so people can easily determine if they need to review or FW
  - Process reference docs
  - JIC overview w/more info on process, routing, etc. (March 23 slides)
  - Add the JIC clearance table at the bottom of your docs
- **All COVID-19-related tweets from FDA official accounts need to be cleared by JIC (including OCC) before posting.** To expedite this, please send draft tweets in batches, where possible, to: 2019nCoVFDAIMGJICSocial@fda.hhs.gov

**TODAY’S FOCUS DISCUSSION** (Second half of meeting)
- Hot topics for the group?
- Strategy / forward look

**COMMS PIPELINE— for each item below, chime in on plans for:**
- Press
- Social
- Other external comms (e.g., consumer, Voices)
- Stakeholder
- Web
- Internal

**Standing item:**
- What is Dr. Hahn up to today? (press, media, etc. – need for various report-outs)
  - On-camera interview w/One America News Network today
  - Press briefing today at WH ~ 5 pm

**Released today, March 31**
- Press statements – Coronavirus (COVID-19) Updates:
  - Daily Roundup March 31, 2020 - Includes information about ...
**Likely today, March 31**

- Web updates:
  - CTP statement on court filing/pushing back May 12 deadline
  - CVM: Web landing page for veterinary and animal food and drug guidance
  - CDRH: New web page / updates to existing page: FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data (target March 31)
  - CDRH: EUAs coming soon: Co-Diagnostics
  - Update CVM FAQs - Animal Food & COVID-19
- Stakeholders:
  - CDRH: Update to masks and respirators guidance, expected March 31

**Likely tomorrow, April 1**

- Press statements - Coronavirus (COVID-19) Updates:
  - Daily roundup April 1, 2020
  - Blood donor guidance (target April 1) w/potential media telebriefing
  - Media Briefing: FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19 (April 1, 10:15 a.m.)
- Web updates:
  - CDRH:
    - Device shortages web page (target April 1)
    - Letter to HCPs on eye protection, and head and shoe covers (target April 1)
  - Stakeholders:
    - CDRH: Thermometers policy, expected April 1
  - Consumer & patient updates:
    - Stakeholder comms for patients/HCPs w/a variety of chronic conditions (target March 31/April 1)

**Released yesterday, March 30**

- Press statements – Coronavirus (COVID-19) Updates:
  - Daily Roundup March 30, 2020 - Includes information about EUAs, and enforcement policies to help expand the availability and capability of sterilizers, disinfectant devices and air purifiers, and expand the availability of gowns and other protective apparel
  - FDA expedites review of diagnostic tests to combat COVID-19
  - FDA on Signing of the COVID-19 Emergency Relief Bill, Including Landmark Over-the-Counter Drug Reform and User Fee Legislation
  - OpEd CNN: What we at the FDA are doing to fight Covid-19 (Hahn)
- Web pages:
  - CDRH new and updated FAQs on Diagnostic Testing for SARS-CoV-2.
• EUAs:
  o Two New Diagnostic EUAs posted (Qiagen, NeuMoDx) + CDC amendment
• Stakeholders
  o Cross-cutting: Updated guidance, Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, with an appendix adding questions and answers
  o CDRH: Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency
  o Listserv messages/social media on QAs for clinical trials during COV19 (updated guidance to add QAs)
  o CDER: Updated Master List of Reactive Q&As for Hand Sanitizer Guidances
  o CDER: Email to Trade Press Constituents Re: CDER Staff email about Over-the-Counter Monograph User Fee Act Signed Into Law
• Internal USG: Provided Coronavirus Treatment Acceleration Program (CTAP) one-pager for White House, and TPs to inform POTUS remarks

Pending release, March 31-April 4 [all internal confidential]
• Press statements - Coronavirus (COVID-19) Updates:
  o Daily roundups
  o FDA Continues to Accelerate Development of Novel Therapies for COVID-19 (new timing: target this week)
  o CDRH:
    o Webinar on EUAs for ventilators and ventilator support accessories (target TBD)

(b)(4)
• Other EUAs coming soon: ...
  o Upcoming IIE Guidances:
    ▪ Infusion Pumps policy, expected April 2
  o CDER:
    o Guidance on PPE for pharmacy compounding (target TBD)
  o CBER:
    o Updated web posting to HCT/P establishments on COVID-19
  o Press statements:
    ▪ Convalescent plasma w/ info on Red Cross role (target April 2 or 3) + stakeholder messages
  o CFSAN:
    o Foods media telebriefing: may happen later this week, a good evergreen media piece we can do at any time
  o CVM:
    o FAQs for main FDA COVID-19 page regarding pets and coronavirus
  o ORA:
    o ...
• Consumer & patient updates:
  (b)(5)
  o New weekly CU featuring new additions to COVID-19 Q&A page

• Web updates
  o FDA Voices: PHS role in response
  o COVID-19 medical countermeasures (cross-cutting, including regulatory science) (target April 3)
  o New web page Coronavirus Treatment Acceleration Program (CTAP), in conjunction with press release
  o ...
• Stakeholder:
  o Planning additional stakeholder calls, similar to successful March 28 CMS call with Drs. Hahn, Shah and other FDA experts
**Routine/daily/weekly activities:**
- Daily - Prepared talking points for Commissioner Hahn for daily White House Task Force and press briefing
- Daily - Prepared/posted tweets/graphics on above topics for Commissioner and FDA accounts
- 2x/weekly (Wed & Fri): COVID-19 response recap emails to stakeholders
- Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA

**MEETING REPORT OUT (see Op Tempo for dial-in #s)**
- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- White House press conference/TF
- NICCL calls (daily 10:15 a.m.)
- Latest AEG discussions

**Pending, from previous discussions**
- FDA outreach to diverse populations (Gloria Sanchez-Contreras, OMA)
- CVS’s request for national guidance on recommended prescription limits for certain drugs (proactive FDA messaging / what we are doing w/stakeholders on this)
- OMA working on a PR

**MEDIA MONITORING**
- See NICCL JIC social listening reports + other files in NICCL JIC folder

**Reviews**
*Note: This table includes mostly items still in JIC/IMG review, to help JIC/IMG members easily keep track of outstanding reviews. It is NOT a comprehensive list of all pending comms. (Short turnaround reviews that happen after ~4 p.m. with deadlines before ~9 a.m. the following day are not included.)*

<table>
<thead>
<tr>
<th>Comm</th>
<th>Clearance Due</th>
<th>Contact (JIC)</th>
<th>Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)</th>
<th>Center(s) Responsible</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>White House TPs (folder – new location)</td>
<td>Daily by 12 pm (time may vary)</td>
<td>Stephanie Caccomo/ Carly McWilliams</td>
<td>All</td>
<td>All</td>
<td>Note: These do evolve and shift throughout the day as we are asked to add additional content.</td>
</tr>
<tr>
<td>Daily round-up press statement March 31</td>
<td>3:00 p.m. daily</td>
<td>Britney Manchester</td>
<td>All</td>
<td>OCET</td>
<td>Add your own plain language bullets about your center’s comms of the day – new process</td>
</tr>
<tr>
<td>MCMi weekly stakeholder email March 31</td>
<td>March 31, noon</td>
<td>April Finnen</td>
<td>JIC/IMG</td>
<td>OCET</td>
<td>Recap of cleared materials + 3D printing tweet thread</td>
</tr>
<tr>
<td>Comm</td>
<td>Clearance Due</td>
<td>Contact (JIC)</td>
<td>Stage in process (JIC/IMG, OCC, AEG, ASPA, WH)</td>
<td>Center(s) Responsible</td>
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<tr>
<td>PREDICT Question from Oversight</td>
<td>April 2 COB</td>
<td>Caitlin Pennington/ Matthew Locked</td>
<td>JIC/IMG</td>
<td>CDER</td>
<td></td>
</tr>
<tr>
<td>House O&amp;R Letter to AMA and CDC regarding Testing</td>
<td>April 3 12 PM</td>
<td>Caitlin Pennington/ Matthew Locked</td>
<td>JIC/IMG</td>
<td>CDRH</td>
<td></td>
</tr>
<tr>
<td>Rep. Roy PPE inspections letter</td>
<td>April 10 COB</td>
<td>Caitlin Pennington/ Matthew Locked</td>
<td>JIC/IMG</td>
<td>CDRH</td>
<td></td>
</tr>
<tr>
<td>Rep. Quigley (multi member) letter re blood donations</td>
<td>April 10 COB</td>
<td>Caitlin Pennington/ Matthew Locked</td>
<td>JIC/IMG</td>
<td>CBER</td>
<td></td>
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</tbody>
</table>

**FUTURE COMMS**

| Daily tweets (including evergreen + weekends)                       | Daily before 3:00 p.m. | Abby Capobianco / Erin Ruberry | All | Ongoing; time-sensitive Commissioner tweets need to be AEG-cleared before 3:00 p.m. daily |
| WORKING COPY of the TPs                                              | Daily by 3 p.m. JIC input | Alex Wohl | JIC/IMG | All |

April Finnen  
IMG JIC Lead  
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)  
U.S. Food and Drug Administration  
Desk: 240-402-4470  
EOC: 301-796-8281 (hours at EOC: Mon. & Thurs. 9:00 a.m. – 11:30 a.m., 1:00 – 3:00 p.m.)  
Cell: (b)(6) Call this # or IM/Skype to reach me  
Email: april.finnen@fda.hhs.gov  
JIC (Joint Information Center) email: 2019-nCoVFDAIMGJIC@fdahhs.gov  

[FDA Logo]

FDA-OSJI-FOIA-2020-3541_00007063
Thank you Marli---

I am sharing this review with others---Bill

This minireview was written by my former mentor. She has worked with coronaviruses for more than 50 years and is a member of the National Academia of Science.
Thank you Denise---Bill

DONOTDISTRIBUTE—CONTAINSON-PUBLIC&COMMERCIALCONFIDENTIALINFORMATION(inred)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications

- Device shortages web page - target 04/01
- Letter to HCPs on eye protection, and head and shoe covers - target 04/01
- Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
- CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target this week
- Potential EUA for vaporized hydrogen peroxide, so hospitals may be able to re-sterilize N95s, possibly up to 20 times target ~mid-week

Medical Product Development & Availability

DIAGNOSTICS
- Pre-EUAs: 249 [+14]
- LDTs: 112 [+2] LDT firms have indicated that they have completed validation and will initiate testing
- EUAs:
  - Submissions: 88 [+9] (2 withdrawn [b](4) no data)
  - Amendments: 12 [+2] requests, 5 have been granted; 2 required re-issue of the original EUA
  - Issued: 22 [+2] [22 [+2] molecular; 0 serological]

PPE: Authorized an amendment to Battelle’s EUA allowing them to operate their decon system at multiple locations

VENTILATORS: Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)

EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments

NEW DEVICE GUIDANCES
- Enforcement Policy for Sterilizers, Disinfectant Devices, and Air Purifiers During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency
- Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency

HUMAN DRUGS: 26 [+2] pre-IND, 8 IND, 0 [-1] Pre-EUA, 1 [-1] EUA request; 1 EUA issued (chloroquine/hydroxychloroquine)
- Remdesivir: 574 EIND requests authorized to date; ACTT trial - 253 (+31) patients enrolled (+40 target), 37 cases...

HAND SANITIZER: CDER/OMQ has been contacting manufacturers that are large producers of hand sanitizers [b](4) can manufacture a large quantity of hand sanitizer and will partner with the Red Cross [b](4) are also interested and will consult with OMQ when the API ethanol guidance is released.

[b][b]: EUA submissions should be submitted within 15 working days of FDA notification
[b][b]: Resulting from the new Regulatory relief policy update
BIOLOGICS: 17 [+1] pre-IND, and 1 IND

Inspections
• ORA Inspections: ORA continues to accomplish inspections that are deemed Mission Critical and ORA IMG Reps continue to triage local field inquiries from states, industry, and other agencies into IMG through RFI process.

Medical Product Supply Chain[3]

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<td></td>
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Fraudulent Products
  - 3 issued today: (1) Halosense Inc., (2) JRB Enterprise Group Inc. DBA Anti-Aging Bed, and (3) FullerLifeC60 LLC

Food Safety
• Nothing to report

Legislative Activities
• Briefings/Hearings Today: N/A
• Upcoming Briefings/Hearings: N/A

[3] Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

[4] China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain
Communications

- **Released today:**
  - Press statements - Coronavirus (COVID-19) Updates:
    - FDA expedites review of diagnostic tests to combat COVID-19
    - FDA on Signing of the COVID-19 Emergency Relief Bill, including Landmark Over-the-Counter Drug Reform and User Fee Legislation
  - Stakeholders
    - Cross-cutting: Updated guidance, Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic, with an appendix adding questions and answers
    - CDRH: Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency
    - Listserv messages/social media on QAs for clinical trials during COV19 (updated guidance to add QAs)

Operations

- PHS Deployments: 169 (+8) officers are deployed; 57 (-9) officers are rostered to deploy

Requests for Information (RFIs)[8]

- Total Received: 125 (+10)
- Total Pending: 22 (18%)
- Total Resolved: 103 (+5) [82%]

External Situation Reports

- FEMA: NRCC Senior Leadership Brief as of 5:00 p.m. ET, March 30, 2020

---

[8] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/30/2020
From: Pillai, Segaran [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1DSE546783D4445FA315D858E0C92D47-SEGARAN.PIL]
Sent: 3/31/2020 3:22:51 PM
To: Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/cn=85fec0be0694803be603be97c7b4adb-HINTOND]
Attachments: COVID 19_Fact Sheet_v1_03312020_244pm_final.docx

Here it is.
DO NOT DISTRIBUTE – CONTAINS NON-PUBLIC & COMMERCIAL CONFIDENTIAL INFORMATION (in red)

Upcoming Policy Activities, Enforcement Actions, Approvals, and Communications
• Device shortages web page - target 04/01
• Letter to HCPs on eye protection, and head and shoe covers - target 04/01
• Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests (April 1)
• CBER is preparing 4 guidances to help relax limitations on blood donors during the COVID-19 pandemic - target 04/01

(b)(4) (b)(5)
• Webinar on EUAs for ventilators and ventilator support accessories in planning (target TBD)
• Request from the Embassy of Pakistan to be included in the list of countries covered by the EUAs for remdesivir and Abbott’s diagnostic test is being considered by CDER.

Medical Product Development & Availability
DIAGNOSTICS
• Pre-EUAs: 261 [+12]
• LDTs: 117 [+5] LDT firms have indicated that they have completed validation and will initiate testing
• EUAs:
  – Submissions: 100 [+12]
  – Amendments: 12 [+2] requests, 6 [+1] have been granted; 2 required re-issue of the original EUA
  – Issued: 23 (22 molecular; 1 [+1] blanket EUA for molecular tests; 0 serological)
• Manufacturer Test Notifications[1]: 37 [+3] firms have notified us, 33 [+3] serology and 4 PCR.
PPE: CDRH is evaluating 24 non-NIOSH-approved respirator EUA requests for KN95s that indicate they have the European CE mark or the Australian Register of Therapeutic Goods Certificate of Inclusion.
VENTILATORS: CDRH authorized the addition 4 ventilator products to Appendix B of the ventilator EUA
EXTRACORPOREAL BLOOD TREATMENTS: CDRH is drafting an EUA for extracorporeal blood treatments
• Remdesivir: 589 [+15] EIND requests authorized to date; ACTT trial - 274 (+21) patients enrolled (440 target) at 37 sites

(b)(4)
• Convalescent Plasma: CBER has granted—and continues to grant—numerous EINDs for convalescent plasma

Inspections
• ORA Inspections:

[1] EUA submissions should be submitted within 15 working days of FDA notification
[2] Resulting from the new Regulatory relief policy update
[3] 1 EUA request is for a product already available under IND
ORA sent 20 requests for records to firms pursuant to authority under 704(a)(4) of the FD&C Act. 17 firms confirmed receipt of the request. To date, 1 site sent all records requested & 7 others submitted partial records.

OEIO and DSS has increased our surveillance of products manufactured or shipped from firms whose inspections have been postponed.

- **CBER**: FDA/CBER continues to work to ensure cGMP compliance by seeking potential solutions when inspections and FDASIA 706 authority are not possible.
- **CDER**: Applications for albuterol MDI and lopinavir/ritonavir (a President’s Emergency Plan for AIDS Relief (PEPFAR) tentative approval resubmission) have been prioritized. An assessment of manufacturing for an albuterol MDI was acceptable. An API facility for lopinavir/ritonavir recently received a warning letter.

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### Medical Product Supply Chain[^1]

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<td>52 (89%)</td>
<td>No negatively impacted firms, no supply chain disruptions</td>
</tr>
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<td>Human Drugs</td>
<td>183</td>
<td>170 (93%)</td>
<td>No major supply chain disruptions. (One respondents has reported a drug shortage associated with the COVID-19 outbreak. Drug product is not medically necessary. Other oral beta-blockers can be used as alternatives.) All the pending chloroquine, hydroxychloroquine, and azithromycin ANDAs have been requested for prioritization. Albuterol MDI will be added to this list soon.</td>
</tr>
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<td>N95s</td>
<td>23</td>
<td>12 (52%)</td>
<td>9 firms report being adversely affected. Common concerns include insufficient raw materials, backorders, export restrictions, workforce shortages, and government nationalization of their facilities.</td>
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<td>42</td>
<td>28 (67%)</td>
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<td>59</td>
<td>33 (65%)</td>
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<td>7 (44%)</td>
<td>5 firms report being adversely affected. Common concerns were that the company had closed, export restrictions, employee shortages, raw material shortages, and government restrictions.</td>
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<td>294</td>
<td>104 (35%)</td>
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<td>62</td>
<td>5 (8%)</td>
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<td>340</td>
<td>240 [+] (71%)</td>
<td>24 adversely affected. Manufacturing issues that include but not limited to workforce availability, transportation delays, and longer lead times with suppliers.</td>
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<td>94</td>
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### Fraudulent Products

- **Warning Letters**: 13 (+1) issued; 44 pending
- 1 issued today to Neuro XPF for a CBD product.

### Food Safety

- **CFSAN released two guidance documents:**
  - FDA Provides Flexibility Regarding Labeling Requirements for Menus During the COVID-19 Pandemic

[^1]: Shortage / availability concerns reflect best professional judgment, based on assessments of available data from manufacturers and supply chain participants, and are intended to be updated weekly. Remediation actions are updated daily. Details are in the body of the report.

[^2]: China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain

**Legislative Activities**

- **Briefings/Hearings Today:** N/A
- **Upcoming Briefings/Hearings:**
  - 4/2, 2:00PM: FEMA Region III Bicameral Hill member and staff briefing; FDA briefer is TBD.
  - 4/3, 2:00PM: Bicameral Hill member and staff briefing; FDA will be available for Q&A; Dr. Shah will represent FDA.

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- **Released today:**
  - Web updates:
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    - Added What's New section on CFSAN COVID-19 FAQ page to highlight new info.
    - CVM: CVM landing page for COVID-19
    - CVM: Industry FAQs: Animal Food Safety and the Coronavirus Disease 2019 (COVID-19)

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- Total Received: 141 (+16)
- Total Pending: 24 [17%]
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---

[6] Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/31/2020
Hi Michael and April,

Pillai (OLS) drafted the attached COVID19 FACT Sheet - please determine how best to share present – webpage/SitRep?

Thank you,

Denise

Please use this version. I had to fixed a spelling error.

Pillai
From: Araojo, Richardae /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDI9O6F23SPDLT)/CN=RECIPIENTS/CN=0474CF3E9AEA4E32980CA8F3B4AD2C1E-ARAOJO
Sent: 3/31/2020 9:50:37 PM
To: Hinton, Denise /o=ExchangeLabs/ou=Exchange Administrative Group (FYDI9O6F23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND
Subject: Re: FDA 2019-nCOV SITREP - 31 March 2020

Thanks

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: March 31, 2020 at 8:14:28 PM EDT
To: Araojo, Richardae <Richardae.Araojo@fda.hhs.gov>
Subject: FDA 2019-nCOV SITREP - 31 March 2020

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5 China, South Korea, Taiwan, Thailand, Singapore, Hongkong, Italy, Germany, Japan, France, and Spain
6 Planning Section RFI Tracker of external RFIs as of 12:00 PM (ET) on 03/31/2020
Thank you!

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 5:00 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Ipsum EUA

This is another PCR test, not the serology, ready for signing. Thanks.

Elizabeth Sadove
Director, MCM Regulatory Policy
Office of Counterterrorism and Emerging Threats
Food and Drug Administration
Okay, I think I can do that for the diagnostics and for the non-NIOSH products I think I can just list the countries.

<table>
<thead>
<tr>
<th>Jurisdiction</th>
<th>Performance Standard</th>
<th>Acceptable product classifications</th>
<th>Standards/Guidance Documents</th>
<th>Protection Factor ≥10</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brazil</td>
<td>ABNT/NBR 13698:2011</td>
<td>PFF3, PFF2</td>
<td>Fundacentro CDU 614.894</td>
<td>YES</td>
</tr>
<tr>
<td>Europe</td>
<td>EN 149-2001</td>
<td>FFP3, FFP2</td>
<td>EN 529:2005</td>
<td>YES</td>
</tr>
<tr>
<td>Japan</td>
<td>JMHLW-2000</td>
<td>DS/DL3</td>
<td>JIS T8150: 2006</td>
<td>YES</td>
</tr>
<tr>
<td>Korea</td>
<td>KMOEL-2017-64</td>
<td>Special 1st</td>
<td>KOSHA GUIDE H-82-2015</td>
<td>YES</td>
</tr>
<tr>
<td>Mexico</td>
<td>NOM-116-2009</td>
<td>N100, P100, R100, N99, P99, R99, N95, P95, R95</td>
<td>NOM-116</td>
<td>YES</td>
</tr>
</tbody>
</table>

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 8:45 PM
To: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: COVID19 EUAs

Okay, I will work on figuring out a way to integrate the list of everything under the EUAs.
For the umbrella EUAs we need to list every product that has been approved under it and keep updating. From my perspective I think it needs to be one-stop-shopping, not to have to click on a link. Same for PPE and ventilators.

Format looks great and very user friendly.

From: McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Sent: Wednesday, April 1, 2020 5:15 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: COVID19 EUAs

McWilliams, Carly has shared a OneDrive for Business file with you. To view it, click the link below.

[20200401 COVID19 EUAs.docx]

Keagan and Stacy, I just got this through occ—I have inserted the latest actions (That we haven’t posted/authorized yet) so it should be completely up to date tomorrow. Can you both look to make sure this hits the mark?
From: Hinton, Denise (O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA08E0694803BE6030E97C7B4ADB-HINTOND]  
Sent: 4/1/2020 9:43:37 PM  
To: Sadove, Elizabeth (O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Mair, Michael (O=ExchangeLabs/OU=Exchange Administrative Group (FYDIBOHF23SPDLT)/CN=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]  
Subject: FW: Cellex EUA  
Attachments: 2-EUA200058 Letter of Authorization .doc; 5-EUA200058 qSARS-CoV-2 Rapid Test Package Insert.FINAL.docx; 4-EUA200058 Patient Fact Sheet (002)_CD.docx; 2-EUA200058 Letter of Authorization_.pdf

Thanks for sending in advance Liz.

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>  
Sent: Wednesday, April 1, 2020 9:28 PM  
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
Subject: Cellex EUA

I’m sending to you the Cellex letter for signing. This is the first serological test. We are still working on the HCP fact sheet. It will be done in 10 minutes, and I’ll forward so you will have had the whole package. Thanks.

Elizabeth Sadove  
Director, MCM Regulatory Policy  
Office of Counterterrorism and Emerging Threats  
Food and Drug Administration
Thanks I d

From: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, April 4, 2020 3:49 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>

Subject: RE: Flagging: Serology test statement, to post today

Sending to him now!

Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Dee ••••••••••••••
Cell (b)(6)
stephanie.caccomo@fda.hhs.gov

Thx, did Anand review?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Saturday, April 4, 2020 11:21 AM
To: Caccamo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Block, Molly <Molly.Block@fda.hhs.gov>

Subject: RE: Flagging: Serology test statement, to post today
Hi! Attached and copied below—statement explaining serology tests, our policy and clarifying the high-complexity lab and teasing forthcoming NCI efforts to validate. if you’d like to provide comment, please let me know in next few hours. I’m continuing clearance to HHS/VP, but can reconcile edits. Will send to Dr. Hahn in a bit as well.
(b)(5)
Hi Denise—I can send this to the CDER leadership team on these products if helpful.

Dear Disaster Leadership Group Members and Colleagues:

Thank you for your participation in COVID-19 Disaster Leadership Group (DLG) Meetings.
We ask that DLG meeting participants ensure leadership within their respective HHS Staff and Operating Divisions are briefed on these materials, and that you do not forward this material beyond the distribution of this message. Please address any questions related to this request to the DLGDESK Resource Mailbox at DLGDESK@hhs.gov.

Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
From: Hinton, Denise [mailto:Denise.Hinton@fda.hhs.gov]
Sent: Thursday, April 9, 2020 5:55:21 PM
To: Mair, Michael [mailto:Michael.Mair@fda.hhs.gov]; Lenihan, Keagan [mailto:Keagan.Lenihan@fda.hhs.gov]; Courtney, Brooke [mailto:Brooke.Courtney@fda.hhs.gov]
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

Thanks for update and I’ll look for it this evening.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 4:39 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

Hi - just FYI - CDER folks are tied up so won’t have comments until this evening. -m

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:29 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

Final is fine, thanks.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:26 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

Hi – comments from FDA SME are not due until 3:30 today – do you want what we have so far or do you want to wait for final comments/edits?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:13 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: FOR REVIEW (b)(3) 42 USC 247d-6b(d), (b)(5)

Yes, I’m copying Michael for awareness since he’ll be compiling the FDA comments. OCC has already provided some comments, but I think we’re still waiting for others.
Can you pull together what you sent over for this data call and share it with me?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: April 8, 2020 at 8:18:04 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: FOR REVIEW

Who on our team is responsible for reviewing and can they provide us with briefing materials?

Thanks

S

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Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
Okay – swimming now

Hi – going through an ocean of emails – was this done? Any updates?

Can you send it to the Commissioner for review and summarize the document for him?

Hi. Attached are consolidated FDA edits/comments

Happy to have any edits/comment from you as well as any thoughts you have on the options. Depending on the extent to which the paper changes based on interagency feedback the paper may come back around for another round of R/C before going to the DLG for discussion on a recommendation – or they might go right to a discussion / decision.

Thx - m
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW

Final is fine, thanks.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:26 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW

Hi – comments from FDA SME are not due until 3:30 today – do you want what we have so far or do you want to wait for final comments/edits?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:13 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: FOR REVIEW

The Commissioner would like to review.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:13 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: FOR REVIEW

Yes, I’m copying Michael for awareness since he’ll be compiling the FDA comments. OCC has already provided some comments, but I think we’re still waiting for others.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 8:37 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: Fwd: FOR REVIEW

Can you pls pull together what you sent over for this data call and share it with me?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
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To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>
Subject: Fwd: FOR REVIEW

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Thanks

S
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Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)

HEALTH AND HUMAN SERVICES (DHHS) | O’Neill House Office Building | 200 C Street SW | Washington, DC 20515
a. (202) 245-0719

(b)(3) 42 USC 247d-6b(d), (b)(5)
That’s me – get your own title!

Should I go higher?

Thinking I should go old-school and sign all of my emails ‘your humble servant’

Not

DR.H to me

SH?

DH did not respond yet
Hi – going through an ocean of emails – was this done? Any updates?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 7:04 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR REVIEW: (b)(3) 42 USC 247d-6b(d), (b)(5)

Can you send it to the Commissioner for review and summarize the document for him?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 6:23 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: FOR REVIEW: (b)(3) 42 USC 247d-6b(d), (b)(5)

Hi. Attached are consolidated FDA edits/comments

Happy to have any edits/comment from you as well as any thoughts you have on the options. Depending on the extent to which the paper changes based on interagency feedback the paper may come back around for another round of R/C before going to the DLG for discussion on a recommendation – or they might go right to a discussion / decision.

Thx - m

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:29 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW: (b)(3) 42 USC 247d-6b(d), (b)(5)

Final is fine, thanks.

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:26 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW: (b)(3) 42 USC 247d-6b(d), (b)(5)

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Sent: Wednesday, April 8, 2020 9:13 AM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Subject: RE: FOR REVIEW: (b)(3) 42 USC 247d-6b(d), (b)(5)

The Commissioner would like to review.

From: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Sent: Wednesday, April 8, 2020 9:13 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>

Subject: RE: FOR REVIEW: (b)(3) 42 USC 247d-6b(d) , (b)(5)

Yes, I’m copying Michael for awareness since he’ll be compiling the FDA comments. OCC has already provided some comments, but I think we’re still waiting for others.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, April 08, 2020 8:37 AM
To: Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>

Subject: Fwd: FOR REVIEW: (b)(3) 42 USC 247d-6b(d) , (b)(5)

Can you pls pull together what you sent over for this data call and share it with me?

Sent from my iPhone

Begin forwarded message:

From: "Hahn, Stephen" <SH1@fda.hhs.gov>
Date: April 8, 2020 at 8:18:04 AM EDT
To: "Lenihan, Keagan" <Keagan.Lenihan@fda.hhs.gov>

Subject: Fwd: FOR REVIEW: (b)(3) 42 USC 247d-6b(d) , (b)(5)

Who on our team is responsible for reviewing and can they provide us with briefing materials?

Thanks

S

From: DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>
Date: April 7, 2020 at 11:48:17 AM EDT
To: Stannard, Paula (OS) <Paula.Stannard@hhs.gov>, Kadlec, Robert P (OS) <Robert.Kadlec@hhs.gov>, Grigsby, Garrett G (OS) <Garrett.Grigsby@hhs.gov>, Kerr, Lawrence (OS) <Lawrence.Kerr@hhs.gov>, Chang, William (OS) <William.Chang@hhs.gov>, Sherman, Susan (OS) <Susan.Sherman@HHS.GOV>, Ray Gorrie, Jennifer (OS) <Jennifer.Ray-Gorrie@fda.hhs.gov>, Strom, John (OS) <John.Strom@fda.hhs.gov>, Patel, Anita (CDC) <bop1@cdc.gov>, Ethier, Kathleen A (CDC) <kbe0@cdc.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Mair, Michael <Michael.Mair@fda.hhs.gov>, Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>, Collins, Francis S (NIH) <collinsf@od.nih.gov>, Fauci, Anthony S (NIH) <afauci@niaid.nih.gov>, Marston, Hilary D (NIH) <hilary.marston@nih.gov>, Shuy, Bryan (OS) <Bryan.Shuy@fda.hhs.gov>, Yeskey, Kevin (OS) <Kevin.Yeskey@hhs.gov>, Bright, Rick (OS) <Rick.Bright@hhs.gov>, Disbrow, Gary (OS) <Gary.Disbrow@hhs.gov>, Lambert, Linda (OS) <Linda.Lambert@hhs.gov>, Adams, Steven A (CDC) <saa1@cdc.gov>, Gorman, Susan E (CDC) <spg4@cdc.gov>
Cc: Phillips, Sally (OS) <Sally.Phillips@hhs.gov>, DeBord, Kristin (OS) <Kristin.DeBord@hhs.gov>, Dodgen, Daniel (OS) <Daniel.Dodgen@HHS.GOV>, Meredith.L.Austin@usbordencg.mil <Meredith.L.Austin@usbordencg.mil>, Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>, Blatner@fda.hhs.gov <Biatner@fda.hhs.gov>, Shirley, Mayo <Mayo.Shirley@fda.hhs.gov>, DLGDESK (HHS/ASPR/OPP) <DLGDESK@hhs.gov>

Subject: FOR REVIEW: (b)(3) 42 USC 247d-6b(d) , (b)(5)

Dear Disaster Leadership Group Members and Colleagues:

Thank you for your participation in COVID-19 Disaster Leadership Group (DLG) Meetings (b)(3) 42 USC 247d-6b(d) , (b)(5)

(b)(3) 42 USC 247d-6b(d) , (b)(5)
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Respectfully,

Dan

Daniel Dodgen, Ph.D.
Senior Advisor
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Office of Strategy, Policy, Planning and Requirements (SPPR)
From: Hinton, Denise [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]

Sent: 4/10/2020 12:02:18 AM

To: Mair, Michael [O=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]

Subject: FYSA: WHTF Materials 4/9 Internal Confidential

Attachments: 20200409 WHTF.docx; CovidVitals_08 APR 2020.docx

Background

20200409
WHTF.docx

Vitals

CovidVitals_08
APR 2020.docx
From: McWilliams, Carly [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP
(FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=868C7458214244D08424FD441FEA4FDA-CARLYLE.MCW]
Sent: 4/13/2020 11:05:15 AM
To: Lenihan, Keagan [O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bdf521b0105d17d2-Keagan.Leni]; Rom, Colin
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f59636221fa340d697dbd43ee27255fb-Colin.Rom]; Shah, Anand
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Amin, Stacy
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6af-Stacy.Amin]
CC: Olivarria, Frank [O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=cc170092db774423f99990dd6e67057c-Frank.Oliv]; Copeland, Jake
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed23c42b68be990b12ae2c8c-Jakea.Cope]; Sheehy, Janice
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648f7-JSheehy]; Franklin, Joseph
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=ace8af0979a847c59ea26c37c4904883-Joseph.Fran]; Rebello, Heidi
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ae193ca494799ef6234a2cfa0-Heidi.Rebe]; Caliguiri, Laura
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf86f26c0346c9e996932d86ac62e-Laura.Calig]; Caccomo, Stephanie
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32ecb4b80b302c50cf31c8524-Stephanie.C]; Felberbaum, Michael
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cda1a2631b83e69673-Michael.Fel]; Hinton, Denise
[O=ExchangeLabs/OU=Exchange Administrative Group
(FYDIBOHF23SPDLT)/cn=Recipients/cn=e85feca0be0694803be0630e97c7b4adb-HINTOND]
Subject: WHTF Materials 4/13 Internal Confidential
Attachments: 20200413 WHTF.docx; CovidVitals_10 APR 2020.docx

Background

20200413
WHTF.docx

Vitals

CovidVitals_10
APR 2020.docx
Hi Denise,

I am sending this to you as an FYI.

Thank You!

Carmila Lesane  
Correspondence Analyst  
Office Of Executive Secretariat  
301-796-8980  

FDA U.S. FOOD & DRUG ADMINISTRATION
Thanks for calling him at 3:30.
From: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>
Sent: Monday, April 13, 2020 2:03 PM
To: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>
Cc: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Weichold, Frank <Frank.Weichold@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Peryea, Tyler <Tyler.Peryea@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>; Welch, Alice <Alice.Welch@fda.hhs.gov>
Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

That’s great then we will try to find who is communicating with AMY about obtaining payer data sets. We thought it was you. I think Alice will. Is Amy the sole person responsible for this. Is there a transparent process. It is really a once in a lifetime chance to get data sets real experts on AI to work on this as a peer-peer activity. We will have to find out who the person who communicates to AMY is there any transparency in the process on what studies to do.

From: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>
Sent: Monday, April 13, 2020 1:28 PM
To: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>
Cc: Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Weichold, Frank <Frank.Weichold@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Peryea, Tyler <Tyler.Peryea@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>
Subject: FW: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Larry,

I needed to work with you. We need approval from our leadership at FDA OC and CDER first. I am sorry, but Gunther’s opinion/theories are unimportant. I recommend not mixing internal and external email recipients in your emails.

Thanks
Mitra

From: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>
Sent: Monday, April 13, 2020 1:12 PM
To: Rocca, Mitra <Mitra.Rocca@fda.hhs.gov>; Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fda.hhs.gov>
Cc: Martin, David <David.Martin@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>
Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Mitra

I am very sad to hear this. All we needed from you was to present this idea to Amy and let Amy decide, that’s it. We do not need any remapped data models to do this. Gunther No-one has tried to get rid of HL-7 V3 SPL format and his validator more than me. He informed that there was a large hydroxychloroquine study going in Brazil and Brazil may shipped a large quantity of hydroxychloroquine to the US for whatever reason don’t know if that true. This is a worldwide problem and we need people from all over the world to help solve it. I believe there are treatment regimens
out there that can minimize death and placement on a respirator. I believe the Chinese, Koreans, and perhaps even Germans have discovered some things and I think we have a way to discover that as well, the more we collaborate. If that is fine, if you want to take over a coma and he was on a hydroxychloroquine regimen I am pretty sure it did not help him but if may help others. I actually think the public health labs and can prove this with data we have today. EMA and China have not approved hydroxychloroquine but they have approved FAVIPIRA VIR as an antiviral and TOCLIZUMAB as agent to treat or prevent cytokine storm.

In the Netherlands is in you feel the way you do not believe I have screwed up many projects but I please let me know which ones so perhaps I can fix them. I understand that I may be in need of a babysitter and you do not want to be it.

No hard feelings. I hope to continue to my collaboration with Ana to do a swot analysis on proposed drugs. I’ll contact my friend at blue cross and inform her that you will be a point of contact for her. Good luck.

Best

Larry

---

From: Rocca, Mitra <Mitra.Rocca@fdahhs.gov>
Sent: Monday, April 13, 2020 12:32 PM
To: Pappas, Gregory <Gregory.Pappas@fdahhs.gov>; Paraoan, Dianne <Dianne.Paraoan@fdahhs.gov>
Cc: Martin, David <David.Martin@fdahhs.gov>; Callahan, Lawrence <Lawrence.Callahan@fdahhs.gov>
Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Hi Dianne,

I am working with Dr. Abernethy on mapping COVID-19 data elements to various Common Data Models and leveraging the Common Data Model Harmonization (CDMH) infrastructure. There is a webinar led by American Medical Informatics Association (AMIA) at 4:00 pm focusing on joint FDA/NIH COVID-19 activities. I will send you the invitation.

I am not collaborating with Larry Callahan on

(b)(5)

Thanks

Mitra

---

From: Pappas, Gregory <Gregory.Pappas@fdahhs.gov>
Sent: Monday, April 13, 2020 11:08 AM
To: Paraoan, Dianne <Dianne.Paraoan@fdahhs.gov>
Cc: Martin, David <David.Martin@fdahhs.gov>; Rocca, Mitra <Mitra.Rocca@fdahhs.gov>; Callahan, Lawrence <Lawrence.Callahan@fdahhs.gov>
Subject: RE: RWD/RWE and COVID: Sentinel System: Response requested by noon today, Mon, 13 Apr

Dianne,

Did you contact Mitra Roca and Larry Callahan? They are exploring with a group of investigators. I think it is a very worthwhile effort to explore RWE.

I’ve cc’ed them on this response.

Greg
Hi Greg,
Apologies for the requested quick turnaround. CDER received an inquiry about the use of RWD/RWE and COVID-19. Attached is our drafted response. We appreciate CBER's input by noon today.

Thanks!
Dianne
Good afternoon,

The following is being sent to your office for action optional. If a response is issued, please send me a copy for our records.

Regards,

Valerie

Valerie Jackson Watson  
Senior Correspondence Analyst  
FDA Executive Secretariat  
301-796-4685  
valerie.jackson@fda.hhs.gov

“TIMELESS TURTLE – STEADY, DEPENDABLE, STRONG”
• Ebola PCC (Policy Coordinating Committee) meeting held today
  o updates provided about the new EVD cases in the DRC
  o received updates from CDC and USAID and brainstormed actions to support response efforts

• Two COVID-19 IVD EUAs received today from CDRH for signature
  o Rheonix COVID-19 MDx Assay (EUA200240) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal washes, nasal aspirates and bronchoalveolar lavage (BAL) fluid from individuals who are suspected of COVID-19 by their healthcare provider.
  o LabGun COVID-19 RT-PCR Kit EUA Request Package (EUA200430) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal, or oropharyngeal, anterior nasal and mid-turbinate nasal swabs, as well as nasopharyngeal wash/aspirate or nasal aspirate specimens and sputum, from individuals who are suspected of COVID-19 by their healthcare provider.

• COVID-19 Departmental Action Group
  o Provided updates on FDA’s ongoing COVID-19 response efforts: focused on near term priorities, activities, and challenges.
RADM Hinton,

This is the version that was sent to OO for review and editing (if they determined it to be necessary). We'll verify with them, and if no changes will mark this one ‘Final’.

r/

Tom
Attached is the Abbott Alinity test-PCR ready for signature. Thanks, Liz

---

From: McManus, John <John.McManus@fda.hhs.gov>
Sent: Monday, May 11, 2020 5:20 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Hi Elizabeth,

These changes are just the comma in the IFU and the Red-lined changes in the LoA, correct? If this is the case, please accept these changes as they accurately reflect IU of the assay.

Thanks

John

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Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Yes... to the HCP as well. I will have to work with the formatting of the HCP to accept the edits. Did you concur with those as well?

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Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Yes, I concur. Thanks Elizabeth

-John

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Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Yes, I concur. Thanks Elizabeth

-John

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From: Sadove, Elizabeth [O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C62700004F34B9DB362FF286AF4B-SADOVE]
Sent: 5/11/2020 5:45:05 PM
To: Hinton, Denise [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOHF23SPDLT)/CN=Recipients/CN=85feca0be0694803be6030e97c7b4adb-HINTOND]; Mair, Michael [O=ExchangeLabs/OU=Exchange Administrative Group (FYDIOHF23SPDLT)/CN=Recipients/CN=f4511bdad7564d7fa7eadc7961467ab-Michael.Mai]
Subject: FW: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package
Attachments: 2-EUA200572 Abbott Alinity NAT EUA LOA 05112020.doc; 3-EUA200572 Abbott Alinity NAT HCP FS 05112020.docx; 4-EUA200572 Abbott Alinity NAT Patient FS 05112020.docx; 5-EUA2000572 Abbott Alinity NAT IFU Comb 05112020.pdf

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I had no comments to the patient fact sheet.

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To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beale, Jacqueline <Jacqueline.Beale@fda.hhs.gov>

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Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package
Dear Jennifer, Liz, and Claire,

Please find attached for you final review the Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package (EUA20572) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swabs, self-collected at a health care location or collected by a healthcare worker, nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare worker or bronchoalveolar lavage fluid (BAL) from patients suspected of COVID-19 by their health care provider:

1) EUA200572 – Abbott Molecular Inc. cover letter
2) EUA200572 – Letter of authorization
3) EUA200572 - HCP Fact Sheet
4) EUA200572 – Patient Fact Sheet
5) EUA200572 – IFU Alinity m SARS-CoV-2
6) EUA200572 – Lead Reviewer Memorandum

Please note, the Abbott Alinity platform is for use in high and moderate complexity labs. Also, the IFU includes a self-collection kit (for use at a healthcare facility); however, since its use is optional with this test it is not called out specifically in the letter of authorization. Abbott can consider it “authorized” as it is included in the test IFU.

CDRH considers these documents cleared.

Thank you for your continuous collaboration and help,

Tamara

Tamara Feldblyum, M.S., Ph.D.
Branch Chief,
Viral Respiratory and STI Branch
Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6195
Tamara.Feldblyum@fda.hhs.gov
Signed – thanks, Liz.

Best,
Denise
These changes are just the comma in the IFU and the Red-lined changes in the LoA, correct? If this is the case, please accept these changes as they accurately reflect IU of the assay.

Thanks

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Tamara.Feldblyum@fda.hhs.gov
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Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>
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Signed – thanks, Liz.

Best,
Denise

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To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
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Yes, I concur. Thanks Elizabeth

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Sent: Monday, May 11, 2020 2:43 PM
To: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beale, Jacqueline <Jacqueline.Beale@fda.hhs.gov>; McManus, John <John.McManus@fda.hhs.gov>
Subject: RE: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Attached are minor edits to the documents. Please note the need to insert a “comma” in the IFU as well (to mirror the one inserted in the IU statement of the LOA).
I had no comments to the patient fact sheet.

Thanks!

From: Feldblyum, Tamara <Tamara.Feldblyum@fda.hhs.gov>
Sent: Monday, May 11, 2020 1:49 PM
To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sapsford, Kim E <Kim.Sapsford@fda.hhs.gov>; Lowe, Toby A <Toby.Lowe@fda.hhs.gov>; Sauer, Robert <Robert.A.Sauer@fda.hhs.gov>; St. Pierre, Don J. <Don.St.Pierre@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Shuren, Jeff <Jeff.Shuren@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Beale, Jacqueline <Jacqueline.Beale@fda.hhs.gov>; McManus, John <John.McManus@fda.hhs.gov>
Subject: EUA200572 Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package

Dear Jennifer, Liz, and Claire,

Please find attached for you final review the Abbott Molecular Inc. - Alinity m SARS-CoV-2 EUA Request Package (EUA200572) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasal swabs, self-collected at a health care location or collected by a healthcare worker, nasopharyngeal (NP) and oropharyngeal (OP) swabs collected by a healthcare worker or bronchoalveolar lavage fluid (BAL) from patients suspected of COVID-19 by their health care provider:

1) EUA200572 – Abbott Molecular Inc. cover letter
2) EUA200572 – Letter of authorization
3) EUA200572 - HCP Fact Sheet
4) EUA200572 – Patient Fact Sheet
5) EUA200572 – IFU Alinity m SARS-CoV-2
6) EUA200572 – Lead Reviewer Memorandum

Please note, the Abbott Alinity platform is for use in high and moderate complexity labs. Also, the IFU includes a self-collection kit (for use at a healthcare facility); however, since it’s use is optional with this test it is not called out specifically in the letter of authorization. Abbott can consider it “authorized” as it is included in the test IFU.

CDRH considers these documents cleared.

Thank you for your continuous collaboration and help,

Tamara

Tamara Feldblyum, M.S., Ph.D.
Branch Chief,
Viral Respiratory and STI Branch
Division of Microbiology Devices | Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality

CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3106 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Ph: (301) 796-6195
Tamara.Feldblyum@fda.hhs.gov
From: Hinton, Denise /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND 5/11/2020 6:57:37 PM
To: Ross, Jennifer /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ]
CC: Sadove, Elizabeth /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000daf34b9db362ff2b6af4b-SADOVEE]; Mair, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai
Subject: FW: For OCS Signature today: RE: Eko ELEFT (PEUA200768) for OCC/OCET review
Attachments: EUA200768 - Letter of Authorization - 5-11-20 FINAL.docx; EAU200768 - Patient Fact Sheet - 5-11-20 FINAL.docx; EAU200768 - HCP Fact Sheet - 5-11-20 FINAL.docx; EAU200768 - Instructions for Use - 5-11-20 FINAL.docx; EUA200768 - Letter of Authorization - 5-11-20 FINAL.pdf

Signed. Thanks, Jennifer.

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>  
Sent: Monday, May 11, 2020 6:24 PM 
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>  
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>  
Subject: For OCS Signature today: RE: Eko ELEFT (PEUA200768) for OCC/OCET review 

RADM Hinton,  

Please sign this letter authorizing an EUA for software (ELEFT) from Eko Devices Inc. for use as a diagnostic aid to screen for potential cardiac complications associated with COVID-19.  

2 fact sheets and instructions for use are also attached. 

This was cleared by CDRH today and OCC (J.Gibney).  

Thanks,  

Jennifer 

Jennifer Ross, PhD, JD  
Senior Regulatory Counsel  
Office of Counterterrorism and Emerging Threats  
Office of the Chief Scientist / U.S. Food and Drug Administration  
Tel: 240-402-8155  
Jennifer.Ross@fda.hhs.gov
Good morning everyone,

Based on our conversation last week, we’ve revised the scope of the Eko ELEFT EUA. The most recent version of the documents are attached. We did not make any other changes besides the scope, which is described below.

(b)(5)

Please let us know if you have any additional questions or suggestions.

Jacquie
From: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>
Sent: Thursday, May 07, 2020 12:49 PM
To: Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Keegan, Erin <Erin.Keegan@fda.hhs.gov>; Bertram, James <James.Bertram@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Hi Angie,

If the 1:00 pm meeting today is still happening, could you please forward me the invite? I have a couple questions on the Eko EUA.

Thanks,
Jaycie

From: Dennis, Claire <Claire.Dennis@fda.hhs.gov>
Sent: Thursday, May 7, 2020 8:27 AM
To: Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Keegan, Erin <Erin.Keegan@fda.hhs.gov>; Bertram, James <James.Bertram@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>
Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Hi Angie,

Jaycie (copied) will be handling for OCC.

Thanks,
Claire

From: Krueger, Angela C <Angela.Krueger@fda.hhs.gov>
Sent: Wednesday, May 6, 2020 10:23 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Cc: Keegan, Erin <Erin.Keegan@fda.hhs.gov>; Bertram, James <James.Bertram@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
Subject: RE: Eko ELEFT (PEUA200768) for OCC/OCET review

Thanks – could we take some time at the 1 pm meeting tomorrow to discuss? We can invite the relevant team members from our side. OCC – who is assigned to this one and we can invite them as well?

Angie

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Wednesday, May 06, 2020 9:36 PM
To: Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Hi Jacqueline,

It would be helpful to discuss this EUA. How much more information is required to get to approval and how long would that take them? In other cases we have seen that when an EUA is issued, there is no incentive for continued product development, yet FDA and other stakeholders would prefer to have a fully marketed product. Also, how does the clinical management of a COVID-19 patient change as a result of using this device? Those are just some of the questions that I have without reading through everything that you sent. Liz may also have questions.

Thanks,

Jennifer

---

From: Gertz, Jacqueline <Jacqueline.Gertz@fda.hhs.gov>
Sent: Wednesday, May 06, 2020 9:03 PM
To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Dennis, Claire <Claire.Dennis@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Keegan, Erin <Erin.Keegan@fda.hhs.gov>; Bertram, James <James.Bertram@fda.hhs.gov>; Krueger, Angela C <Angela.Krueger@fda.hhs.gov>; Fulmer, Sonja <Sonja.Fulmer@fda.hhs.gov>
Subject: Eko ELEFT (PEUA200768) for OCC/OCET review

Hello OCC and OCET,

We have attached the following documents for the Eko ELEFT EUA for review:

1. Letter of Authorization
2. Fact Sheet for HCP
3. Fact Sheet for Patients
4. Instructions for Use
5. Review Memo

Please let us know if you have any questions or if it would be helpful to discuss this EUA.

Jacquie

Jacqueline Gertz, Ph.D.
Regulatory Advisor
Office of Product Evaluation and Quality
Regulation, Policy, and Guidance Staff
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.
Thanks. I’ll check to see if I need to respond.

I didn’t find anything else, other than this (with the same name):

Richard M. Fleming; Denial of Hearing;
Final Debarment Order


No, I have not received any email like this. I will check on the CT.gov # for other details and circle back.

I do not believe this is a legitimate source; however, have you received these emails as well?

Dear Ms. Denise M Hinton,

As the Chief Scientist for the FDA, who authorized the EUA for Remdesivir, I am inquiring about the actual (original) data used to support the EUA. Specifically, the NCT04280705 data.

As one of the clinical trials including Remdesivir
investigation as a potential treatment for CoVid-19, we would like to make this information available to the IRB for further evaluation and consideration.

Respectfully,

Dr. Fleming

---

Richard M Fleming, PhD, MD, JD

(C) (b)(6)

(skype): fleming-reno

(email) (b)(6)

This electronic message is intended to be for the use of the named recipient, and may contain information that is confidential or privileged. This communication may contain protected health information (PHI) that is legally protected from inappropriate disclosure by the Privacy Standards of the Health Insurance Portability and Accountability Act (HIPAA) and relevant California Laws. You can direct questions concerning PHI or HIPAA to the Corporate Compliance and Privacy Officer at (818) 210-6930. If you are not the intended recipient, please note that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this message in error, you should notify the sender immediately by telephone or by return e-mail and delete and destroy all copies of this message.
May 16, 2020

Denise M. Hinton  
Chief Scientist  
Food and Drug Administration

Dear Ma’am:

This letter is in regards to your letter of authorization for emergency use of remdesivir for severe cases of hospitalized covid patients. 

My name is [redacted]. I’m a Nurse Practitioner working in a primary care/urgent care office. I got infected of corona virus on [redacted] which lasted two weeks then my husband got sick as well, we both stayed home and were able to manage. On [redacted] my mother [redacted] 69 years old got sick too and was tested positive for Covid on [redacted] I thought we would be able to manage her symptoms at home but on [redacted] she started to have respiratory distress and her oxygen level desaturated to 60-70s. I called [redacted] and she was brought to the hospital right away. We needed to have a high supply of oxygen, (non-rebreather and high flow oxygen). She was admitted that day and few days later she needed to be put on bipap. She was given Actemra twice and Plasma but no positive result. At this time, she is still at the hospital and has a really bad pneumonia. She requires a combination of non-rebreather and high flow oxygen at day time and bipap at night. On [redacted] I saw your letter of authorization for emergency use of remdesivir for severe cases of hospitalized patients. In that letter, severe cases was defined as those with oxygen level of< 94 on room air, those who needs oxygen supplement and those who are intubated. Two days later after seeing this letter, I spoke to my mother’s doctor, to the Infectious Disease Specialist who can prescribe this medication and requested that my mother be given remdesivir based on the criteria described. I was told that my mother doesn’t fit the criteria because they are only giving it to intubated patients. But why would they have to wait for the patient to get intubated before giving the remdesivir? In some hospitals and trials they are giving this to severe cases with the goal of avoiding intubation and so far has positive outcome.

My mother has been at the hospital for over three weeks with no clinical improvement. I appreciate their effort of delaying intubation and all the care that my mother receives but I’m also requesting that she receives remdesivir treatment. In your letter, it was also mentioned that for non-intubated patient, they can get the 5 day dosing and if no improvement can extend up to 10 days.

Am I wrong to request remdesivir treatment for my mother? She is suffering and can barely eat because she can’t breath when she takes off the non-rebreather if she is only on high flow oxygen. I understand that there is no treatment for corona virus infection and all of the treatments are at clinical trial stage. The remdesivir so far based on the clinical trial sponsored by National Institute of Allergy and Infectious Disease (NIAID) has shown faster recovery of patient with advanced covid cases. I just hope that it’s not late for my mother to receive remdesivir. She is on her 4th week since her symptoms started. At this point with no clinical improvement in her condition, why can we try all possible treatment to make her better?
I am writing this letter to advocate for my mother and possibly for all other covid patients with severe cases who have met the criteria to receive possible treatment but hospitals are not willing to provide it.

My mother, located at (b)(6) with telephone number (b)(6), I’m hopeful that she would be home by then.

I appreciate your prompt response to this letter. I’m not sure what else to do for my mother at this point, all I know is I would like her to survive and recover from this corona virus infection.

If you have any question or inquiry, I can be reach at my work number Monday to Friday from 9:00 am to 5:00 pm and out of office hours through my cellphone at (b)(6). You can also email me at (b)(6). Please see attached copy of your letter of authorization for emergency use of remdesevir for patient with severe covid cases.

Thank you very much.

Sincerely,

(b)(6)
Good morning Patrizia,

I received the following draft manuscript for review and am sending to you for awareness. Any concerns with this moving forward for publication?

From: Weichold, Frank <Frank.Weichold@fda.hhs.gov>
Sent: Tuesday, May 19, 2020 4:24 PM
To: Welch, Alice <Alice.Welch@fda.hhs.gov>; Johanson, Elaine <Elaine.Johanson@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Callahan, Lawrence <Lawrence.Callahan@fda.hhs.gov>; Warren, Matthew <Matthew.Warren@fda.hhs.gov>; Fisher, Robert <Robert.Fisher@fda.hhs.gov>; Szarfman, Ana <Ana.Szarfman@fda.hhs.gov>; Pappas, Gregory <Gregory.Pappas@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Bouri, Khaled <Khaled.Bouri@fda.hhs.gov>
Subject: COVID-19- Famotidine Histamine Mast Cells and Mechanisms v3.4 19May.pdf

Dear Colleagues,
Please find attached draft manuscript FYI and review in context of the ongoing work and collaboration regarding famotidine for COVID19.
Please send me any comments and suggestions by May 22 (COB). Your kind review, timely feedback and help are very much appreciated.
Hoping you and yours are well!
Best wishes.
Frank
301-661-7890
Hi Jeff

Please see below.

Thanks,
Denise

---

From: Schmoyer, Michael W. EOP/OSTP
Sent: Thursday, May 28, 2020 12:52 PM
To: Schwartz, Erica (OS) <Erica.Schwartz@hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: COVID mobile testing assets

Good afternoon Admirals-

Thoughts on below?

V/R,

CAPT Schmoyer

Michael W. Schmoyer, PhD
Assistant Director for Biotechnology & Biosurveillance
National Security & International Affairs Division
Office of Science and Technology Policy (OSTP)
Executive Office of the President
The White House

https://www.whitehouse.gov/ostp/

---

From: Rodgers, Loren E. EOP/WHO
Sent: Thursday, May 28, 2020 12:15 PM
To: Schmoyer, Michael W. EOP/OSTP
Cc: Ludwig, Michael E. COL USA WHMO/WHMU; Hartung, Charles S. CAPT USN WHMO/WHMU
Subject: COVID mobile testing assets
CAPT Schmoyer, 
I have a question about: [redacted] [redacted]
(b)(5) Do you have a moment available for a consultation?

V/r
Loren

Loren Rodgers, PhD
Commander, US Public Health Service
Epidemiologist; TDY to WHMU
WHMU Mobile Phone: [redacted]
CDC Mobile Phone: [redacted]
WHMU Email: lrodgers@cdc.gov
CDC Email: lrodgers@cdc.gov

In Officio Solutis
RADM,

Just wanted to put this on your radar as it is Hydroxychloroquine related. This is big news in the scientific community right now.


Best,

Mike
Dear Dr. Hinton,

Hope this message finds you well.

My name is Davit Mrelashvili, and I am a physician with active medical licenses in 26 states and telemedicine practice in over 150 hospitals across the country.

I am writing you on behalf of myself and many of my colleagues involved in treating COVID-19 patients, as well as creating treatment guidelines nationally, and internationally.

Our recent concern has been the growing evidence regarding Hydroxychloroquine safety and efficacy in Covid-19 patients.

As you are aware, the initial (limited) data at earlier stages of pandemic was promising, and suggested that Hydroxychloroquine could be safe and effective in COVID-19 patients, that resulted in its acceptance at an EUA level. However recently there has been an inflow of surmounting higher quality data, that not only Hydroxychloroquine had no significance difference than placebo in terms of efficiency (in randomized controlled trials), but in some cases was associated with higher mortality (yet a clear direct link not established, yet). Most recently the national randomized study of COVID-19 patients with multiple treatment options RECOVERY, closed the recruitment for Hydroxychloroquine given that same concern.

While we completely understand that FDA provides a general guidance, rather than mandating or directing any particular patient treatment (that is left to the treating physician), we are getting a significant amount of distrust from the families and pushback from the local health care authorities, why we are not offering one of the few allowed treatment options to COVID-19 patients (despite us having an evidence based practice that it should not be offered), as Hydroxychloroquine remains to have an FDA EUA.

Our respectful question/request to you is given the above, whether or not FDA is considering removing the EUA from Hydroxychloroquine in the near future. If not – please let us know that as well, in which case we perhaps will need to seek out more local resources to protect ourselves from increased chances of an unjust litigation from the families of the patients with unfortunate outcomes, as not using the FDA authorized treatment certainly increases the chances of it in high mortality conditions.

I can only imagine the amount of workload and correspondence that you are getting these days, and any response regarding above matter will be much appreciated.

Respectfully,

Davit Mrelashvili, MD
Hi Liz,

All have been signed. Please let me know if I missed any.

Thanks,

Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Saturday, June 6, 2020 7:52 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: Decontamination Letters for signature

As we discussed yesterday, I am sending the attached letters of authorization for the 7 decontamination systems EUAs being reissued. These are ready for signature. I will send back to CDRH as complete packages after you sign. The 2 FFR EUAs will be coming in a separate e-mail.

Thanks!
Sent: 6/14/2020 9:30:08 AM
To: Abram, Anna /o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=f8776068913842327cd9086fcb1a3b-Anna.Abram]; Lenihan, Keagan
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=ee732008ec18466bdf521b00105d7172-Keagan.Lenihan]; Pines, Wayne *
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=0e9f5ce0254041a4896661c0d03c38bef5-Wayne.Pines]
CC: Caccomo, Stephanie /o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Hahn, Stephen
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hahn]; Shah, Anand
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caliguiri, Laura
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi
/o=ExchangeLabs/ou=Exchange Administrative Group
[FYDIOHF23SPDLT]/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: CLOSE HOLD: for review by AM: HCQ EUA, ____(b)(4)____

Good morning. I also agree with Keagan’s suggestion of a ____(b)(5)____

From: Abram, Anna <Anna.Abram@fda.hhs.gov>
Sent: Sunday, June 14, 2020 9:02 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: CLOSE HOLD: for review by AM: HCQ EUA, ____(b)(4)____

Good morning - I concur with Keagan’s suggestion.

Just spoke to Stephanie regarding the ____(b)(5)____

Internal confidential pre decisional draft deliberative

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: June 14, 2020 at 8:05:37 AM EDT
To: Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Cc: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Hahn, Stephen <SH1@fda.hhs.gov>, Abram, Anna <Anna.Abram@fda.hhs.gov>, Shah, Anand <Anand.Shah@fda.hhs.gov>, Hinton, Denise <Denise.Hinton@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: CLOSE HOLD: for review by AM: HCQ EUA, ____(b)(4)____

____(b)(5)____
Stephanie:

Suggestions:

(b)(5)

Hope these suggestions help. Thanks.

Wayne
Hi—

Two press releases for your review. Remdesivir fact sheet update. Plus HCQ EUA revocation. I appreciate review by 9am tomorrow so we can get to HHS/WH.

Also want to urge us to consider a (b)(5)
Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.346.1558
Cell: (b)(6)
stephanie.caccomo@fda.hhs.gov
INTERNAL/DELIBERATIVE
CDER is posting a QA about HCQ action. One of the QAs says below about not recommending using HCQ/CQ. CDER SMEs flagged for me this morning because they feel QA is inconsistent with what we are saying in the PR.

I am ok proceeding as is because I sort of feel like we are talking about what is ultimately up to a physician, flagging for awareness.

Q. What if I am in the middle of treatment with hydroxychloroquine sulfate (HCQ) or chloroquine phosphate (CQ) for COVID-19 under the EUA? Can my treatment continue to completion?

(b)(5)

Press release:
Of note, FDA approved products may be prescribed by physicians for off-label uses if they determine it is appropriate for treating their patients, including for COVID-19.

Stephanie Caccomo
Press Officer
Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk 301.348.1556
Cf. (b)(6)
stephanie.caccomo@fda.hhs.gov
Thanks Liz!

Attached is the final letter ready for your signature. Thanks!

Elizabeth Sadove  
Director, MCM Regulatory Policy  
Office of Counterterrorism and Emerging Threats  
Food and Drug Administration
Dear Dr. Hinton,

Thank you very much for your consideration and understanding.

Regards,
Davit

On Jun 6, 2020, at 2:43 PM, Davit Mrelashvili, MD [RMT/C] <drmrelashvili@soctelemed.com> wrote:

Dear Dr. Hinton,

Hope this message finds you well.

My name is Davit Mrelashvili, and I am a physician with active medical licenses in 26 states and telemedicine practice in over 150 hospitals across the country.

I am writing you on behalf of myself and many of my colleagues involved in treating COVID-19 patients, as well as creating treatment guidelines nationally, and internationally.

Our recent concern has been the growing evidence regarding Hydroxychloroquine safety and efficacy in Covid-19 patients.

As you are aware, the initial (limited) data at earlier stages of pandemic was promising, and suggested that Hydroxychloroquine could be safe and effective in COVID-19 patients, that resulted in its acceptance at an EUA level. However recently there has been an inflow of surmounting higher quality data, that not only Hydroxychloroquine had no significance difference than placebo in terms of efficiency (in randomized controlled trials), but in some cases was associated with higher mortality (yet a clear direct link not established, yet).

Most recently the national randomized study of COVID-19 patients with multiple treatment options RECOVERY, closed the recruitment for Hydroxychloroquine given that same concern.

While we completely understand that FDA provides a general guidance, rather than mandating or directing any particular patient treatment (that is left to the treating physician), we are getting a significant amount of distrust from the families and pushback from the local health care authorities, why we are not offering one of the few allowed treatment options to COVID-19 patients (despite us having an evidence based practice that it should not be offered), as Hydroxychloroquine remains to have an FDA EUA.

Our respectful question/request to you is given the above, whether or not FDA is considering removing the EUA from Hydroxychloroquine in the near future. If not – please let us know that as well, in which case we perhaps will need to seek out more local resources to protect ourselves from increased chances of an unjust litigation from the families of the patients with unfortunate outcomes, as not using the FDA authorized treatment certainly increases the chances of it in high mortality conditions.
I can only imagine the amount of workload and correspondence that you are getting these days, and any response regarding above matter will be much appreciated.

Respectfully,

Davit Mrelashvili, MD
Thank you.

From: Chan, Peter <Peter.Chan@easternhealth.org.au>
Sent: Saturday, July 11, 2020 1:33 AM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: Protective Barrier Enclosures

RADM Hinton:

I am an ICU Specialist in Melbourne, Australia. We were recently gifted a number of protective barrier enclosures which we have gone on to evaluate for aerosol exposure. Our results were recently published in Anaesthesia. (https://onlinelibrary.wiley.com/doi/full/10.1111/anae.15188)

In short, even though our study was small, the results were highly significant pointing towards PBEs increasing, not decreasing your risk of aerosol exposure. Given the increasing evidence of aerosols causing potential COVID infection, I ask that you highly reconsider the EUA for this device until more tests can be done.

I note in your letter that these devices were tested using methods similar to ours – I would suggest you potentially repeat your experiment with a volunteer that coughs, to better simulate in vivo conditions. The results may indeed sway your opinion on these devices as they stand.

Kind Regards,

Dr. Peter Chan
ICU Specialist
Eastern Health
Melbourne, VIC
Australia 3128

Sent from Mail for Windows 10
Friendly reminder on this one

RADM Hinton,

Please sign this letter

This was submitted by CDRH and incorporates edits from OCC (P. Taylor) below.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel
Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov

FDA
U.S. FOOD & DRUG ADMINISTRATION

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, July 13, 2020 2:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature today: 

This was submitted by CDRH and incorporates edits from OCC (P.Taylor) below.

Thanks,

Jennifer
Many thanks, Paige and Jennifer. Please see attached for the final, clean documents. Jennifer, the letter should be ready for RADM Hinton’s signature.

Thanks,
Brittany

Brittany Schuck, Ph.D.
COVID-19 Response Team
Personalized Medicine Policy

OHT7: Office of In Vitro Diagnostics and Radiological Health
Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
White Oak, Bldg. 66, Rm. 3556 | 10903 New Hampshire Avenue | Silver Spring, MD 20993
Tel: 301-796-5199

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From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, July 13, 2020 1:37 PM
To: Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <TimothyStenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft

Sounds good to me.

From: Taylor, Paige <Paige.Taylor@fda.hhs.gov>
Sent: Monday, July 13, 2020 1:29 PM
To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <TimothyStenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>
Many thanks, Jaycie and Jennifer.

We agree with the edits on the letter and memo. Please see attached for revised documents where we have addressed the comments in the letter and memo.

Please let us know if these can be cleaned up and finalized.

Thanks,

Brittany

Brittany Schuck, Ph.D.
COVID-19 Response Team
Personalized Medicine Policy

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To: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft

I had only very minor couple things on the letter. Thanks, Jennifer

Hi all,

Sending OCC comments on the letter and a couple additional minor edit to the memo. Let us know if you have questions.

Thanks,
Jaycie

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Sunday, July 12, 2020 3:05 PM
To: Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft

Hi Paige and team,

Please see attached for revisions to the memo where we have responded to the comments and made corresponding edits, as needed. We have also attached the draft letter for your review.

Please let us know of any additional comments/questions/edits.

Many thanks,
Brittany
Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: https://www.research.net/ cdrhcustomerservice?ID=1912&S=E

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From: Taylor, Paige <Paige.Taylor@fda.hhs.gov>
Sent: Friday, July 10, 2020 2:03 PM
To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>;
Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>;
Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>;
Schenkel, Timothy <Timothy.Schenkel@fda.hhs.gov>;
St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>;
Lias, Courtney H <Courtney.Lias@fda.hhs.gov>;
Garcia, Maria <Maria.Garcia@fda.hhs.gov>;
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Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>;
Beaver, Renee <Renee.Beaver@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft

Our comments on the (b)(4) memo are attached. Thanks

Paige

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Friday, July 10, 2020 9:58 AM
To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>;
Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>;
Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>;
Schenkel, Timothy <Timothy.Schenkel@fda.hhs.gov>;
St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>;
Lias, Courtney H <Courtney.Lias@fda.hhs.gov>;
Garcia, Maria <Maria.Garcia@fda.hhs.gov>;
Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>;
Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>;
Taylor, Paige <Paige.Taylor@fda.hhs.gov>
Subject: RE: FOR REVIEW: draft

Good Morning OCC and OCET colleagues,

For OCC/OCET review and concurrence, please see attached for the draft (b)(4) for (b)(4). Also, per your request, we have attached the emails exchanged with the sponsor during interactive review.
The information and clinical and analytical validation data submitted in the EUA request and through interactive review are not adequate to support issuance of the EUA. As briefly discussed during our call on Wednesday, this one is similar to the (b)(4) memo/letter since the basis of the denial is that the sponsor has not provided adequate information to demonstrate their device is adequately validated for its intended use.

Issuance of this denial in the interest of protecting public health is a priority for CDRH.

Please let us know if you have any questions or would like to further discuss.

Best,
Brittany

Brittany Schuck, Ph.D.
COVID-19 Response Team
Personalized Medicine Policy

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Office of Product Evaluation and Quality
CDRH | Food and Drug Administration
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Tel: 301-796-5199

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From: Hinton, Denise /O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND
Sent: 7/13/2020 3:58:48 PM
To: Ross, Jennifer /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=44ae562ea1d840a3aca172d0cc23f368-RossJ
CC: Mair, Michael /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f451bdad7564d7fac7eadc7961467ab-Michael.Mair); Sadove, Elizabeth /o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6a4f-SADOVEE
Subject: (b)(4)
Attachments: (b)(4)

Thank you

From: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Sent: Monday, July 13, 2020 2:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: For OCS Signature today; (b)(4)

RADM Hinton,

Please sign this letter to (b)(4)

This was submitted by CDRH and incorporates edits from OCC (P.Taylor) below.

Thanks,

Jennifer

Jennifer Ross, PhD, JD
Senior Regulatory Counsel

Office of Counterterrorism and Emerging Threats
Office of the Chief Scientist / U.S. Food and Drug Administration
Tel 240-402-8155
Jennifer.Ross@fda.hhs.gov

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Monday, July 13, 2020 1:49 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>

FDA-OSJI-FOIA-2020-3541_00001992
Many thanks, Paige and Jennifer. Please see attached for the final, clean documents. Jennifer, the letter should be ready for RADM Hinton’s signature.

Thanks,

Brittany
We do not have any further comments on the memo. On the letter,

Otherwise, no changes. So these are ready to finalize and send.

Thanks much

Paige

From: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>
Sent: Monday, July 13, 2020 12:29 PM
To: Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>; Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>
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Subject: RE: FOR REVIEW: draft

Many thanks, Jaycie and Jennifer.

We agree with the edits on the letter and memo. Please see attached for revised documents where we have addressed the comments in the letter and memo.

Please let us know if these can be cleaned up and finalized.

Thanks,

Brittany

Brittany Schuck, Ph.D.
COVID-19 Response Team
Personalized Medicine Policy

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Subject: RE: FOR REVIEW: draft (b)(4)

I had only very minor couple things on the letter. Thanks, Jennifer

From: Gibney, Jaycie <Jaycie.Gibney@fda.hhs.gov>
Sent: Monday, July 13, 2020 10:26 AM
To: Schuck, Brittany <Brittany.Schuck@fda.hhs.gov>; Taylor, Paige <Paige.Taylor@fda.hhs.gov>; OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
Cc: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Flannery, Ellen <Ellen.Flannery@fda.hhs.gov>; Hillebrenner, Elizabeth J <Elizabeth.Hillebrenner@fda.hhs.gov>; Stenzel, Timothy <Timothy.Stenzel@fda.hhs.gov>; St. Pierre, Don J. <don.st.pierre@fda.hhs.gov>; Lias, Courtney H <Courtney.Lias@fda.hhs.gov>; Scherf, Uwe <Uwe.Scherf@fda.hhs.gov>; Garcia, Maria <Maria.Garcia@fda.hhs.gov>; Singleton, Shannon <Shannon.Singleton@fda.hhs.gov>; Beaver, Renee <Renee.Beaver@fda.hhs.gov>
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Many thanks,
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Brittany Schuck, Ph.D.
COVID-19 Response Team
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Paige

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Sent: Friday, July 10, 2020 9:58 AM
To: OCCRequests-COVID19 <OCCRequests-COVID19@fda.hhs.gov>; Ross, Jennifer <Jennifer.Ross@fda.hhs.gov>
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Subject: RE: FOR REVIEW: draft (b)(4)

Good Morning OCC and OCET colleagues,
For OCC/OCET review and concurrence, please see attached for the draft (b)(4) for (b)(4). Also, per your request, we have attached the emails exchanged with the sponsor during interactive review.

The information and clinical and analytical validation data submitted in the EUA request and through interactive review are not adequate to support issuance of the EUA. As briefly discussed during our call on Wednesday, this one is similar to the (b)(4) memo/letter since the basis of the denial is that the sponsor has not provided adequate information to demonstrate their device is adequately validated for its intended use.

Issuance of this denial in the interest of protecting public health is a priority for CDRH.

Please let us know if you have any questions or would like to further discuss.

Best,

Brittany Schuck, Ph.D.

COV-19 Response Team
Personalized Medicine Policy

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