From: Rom, Colin [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F59636221F4340D697DBD43EE27255FB-COLIN.ROM]
Sent: 7/29/2020 7:57:03 AM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; McWilliams, Carly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b68c7458214244d08424fd441fea4fda-Carlyle.McW]
Subject: RE: 7/28- TUESDAY HOMEWORK - INTERNAL CONFIDENTIAL

Thank you. Will send this back to the team

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Wednesday, July 29, 2020 7:53 AM
To: Rom, Colin <Colin.Rom@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; McWilliams, Carly <Carly.McWilliams@fda.hhs.gov>
Subject: Re: 7/28- TUESDAY HOMEWORK - INTERNAL CONFIDENTIAL

Here are my comments on the talkers

1. I'd like us to communicate about the HCQ EUA revocation in a way that better reflects what happened and provide granularity. The EUA was issued at the request of BARDA in order to get donated drug into the system. It was not initiated by FDA and this is an important point that is often overlooked by our stakeholders. Likewise the revocation was requested by BARDA after they reviewed the data. They then requested revocation. That was not a unilateral FDA action.
2. I think the numbers of INDS has increased to over 200 so perhaps we can revise those numbers if accurate.
3. I'd recommend revising the following sentence: The regulatory and scientific process surrounding such a revocation **confirms the strength of the decision-making on an EUA…. To "the regulatory and scientific process surrounding our review and assessment of EUAs during the pandemic, confirms the strength….**

Thanks
Steve

From: Colin Rom <Colin.Rom@fda.hhs.gov>
Date: Tuesday, July 28, 2020 at 10:54 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Erika Anderson <Erika.Anderson@fda.hhs.gov>, Anand Shah <Anand.Shah@fda.hhs.gov>, Heidi Rebello <Heidi.Rebello@fda.hhs.gov>, "Tobias, Lindsay" <Lindsay.Tobias@fda.hhs.gov>, Carly McWilliams <Carly.McWilliams@fda.hhs.gov>
Subject: 7/28- TUESDAY HOMEWORK - INTERNAL CONFIDENTIAL

Dr. Hahn, attached for your review this evening:

- Meeting memo & talking points for call with the American College of Rheumatology

ITEMS FOR YOUR REVIEW

Action: Edit By 9:00am Wednesday

- **ITEM #1: Call with the American College of Rheumatology**

07302020American College of Rheumatology Invited participants.docx
07302020ACRcall.docx

Have a great night!

From: (b) (6)
Sent: 8/7/2020 7:34:13 PM
To: CDER DRUG INFO [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82081760a0544b00be5884dfcf1f96cb-DRUGINFO]
CC: FDA Commissioner [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1e34b2c290a94c4a8d7af884727cd0f8-Commissione]
Subject: Re: Hydroxychloroquine Emergency Use Authorization

Joy,
No, this information has not been helpful. This is probably somewhat of a typical automated response and, I think, shows that no one there is the least bit concerned about saving lives. I hope I am wrong, but I also doubt that Dr. Hahn even saw my original email. So sad!
The studies you refer to have mostly been discredited once peer reviewed. What about more recent studies in our country that have shown good positive results. With all due respect, it is hard for me to understand why a person like Dr. Hahn would not do some research of Hydroxychloroquine on his own and talk to the many, many Doctors and healthcare professionals, (even other countries), who have used the drug a lot in early treatment, in the correct doses, and in combination with other medications, having had tremendous success. I realize this is not the cure all, but it is working for many. I have heard and read countless interviews and testimonies on the use of this treatment. I have heard leading physicians, epidemiologists, and others who are using it and are completely baffled by the response of the FDA. Many indicating the loss of life as a result of the FDA's actions. Others saying if the FDA would publicly reverse their statement or ban and allow this off label use, that thousands of lives would be saved. The statements I have heard are not real recent, which to me means that thousands of lives have already been lost. I do not see how anyone could honestly live with that. There are some pretty dark forces at work out there.
All I can do is to continue to pray that the Lord will open some eyes and hearts and do what is right for the American people, and not succumb to the politicians, drug companies, and other forces. Yes, I believe that is what is happening, if the truth were really known. Like I said in my previous email to Dr. Hahn, who is really controlling you?

So I ask, Dr. Hahn, "In Jesus Name", please step up and do what you know in your conscience is the right thing to do for the lives of many people.
I hope that you, Dr. Hahn, are able to read this response as well as my original email.
Thank you for your service to our country & "God Bless",
(b) (6) (a concerned senior citizen from (b) (6)

p.s. I feel so strongly, that I am including a complete copy of my previous email below:

My concerns about the FDA's stance on Hydroxychloroquine

Dr. Hahn,
I do not know where to begin. I guess I am just very puzzled as to why You and others in the FDA, CDC, Dr. Fauci, are so resistant to HC. It makes me wonder who is actually controlling you all. There are many others, but I refer you to the following link and I hope you will read it in is entirety:

https://www.google.com/url?sa=t&rct=j&q=&esrc=s&source=web&cd=&ved=2ahUKEwiC_tHiwp3qAhXLFjQIHcA3CzoQFjABegQIAhAB&url=https%3A%2F%2Fwww.statnews.com%2F2020%2F06%2F16%2Fhydroxychloroquine-emergency-use-patients-politicians%2F&usg=AOvVaw3q79dhsXgEWo8TFfSzt20M

As a Doctor, I can not believe you are not aware of all the Doctors who are using HC along with other drugs (Azithromycin, Zinc) with great success. I have seen so many interviews, of patients who have credited HC for saving their lives, of Doctors who are using HC and with great success. (In many cases keeping patients out of the hospital and

in many cases by starting patients right when they enter the hospital and preventing the need for a ventilator). There was an interview with a women Doctor in Texas who was prescribing HC along with the other drugs and was amazed at the results. She was treating patients in her outpatient practice and said there where people coming to her from all over, that were in various stages of Covid, and even she could not believe how well the treatment was working. Then one day, she got a call from a CVS Pharmacy and they were not going to fill that patient's prescription. She got them to fill this one, but they said they would no longer do so in the future. The Doctor said she had to scramble to get HC for her patients and was not sure what she was going to do.
I could go on and on. There are many interviews I have watched in the news and many other such stories found on the internet (some videos, some articles), where Doctors have treated patients, in early stages as well as critical stages, with great success.

Many Doctors have expressed their befuddlement with the message you are sending. Some have even stated because of the the results of your actions that many people will die and have died. Some have even said they feel the FDA is corrupt. Some say the FDA and others are in the pockets of the pharmaceutical companies. I certainly hope that is not the case but I myself have certainly wondered what is really going on here.

Then there was the so called "study" of patients in the VA, that turned out to be bogus. They were patient record reviews, never with the patients, done by, as I understand, two Ophthalmologists, and I think one was stated as having a political bias. There were many Doctors absolutely disgusted by it. Why weren't you and why did you not say so.
Then we have the latest one that was a big blow to HC. Are you even aware of who put it out? It was RETRACTED, because of the peer reviews of Doctors and others who actually read it, but the damage was already done. I think this study was probably the one that led to you stating that HC was no longer considered an effective treatment of Covid. This has caused Governor's to ban the off label use in their states, Pharmacies not allowed to fill prescriptions for Covid treatment, limited it's use to hospitals only, Doctors wondering if they will loose their license if they continue to prescribe it for Covid. Even other countries where Doctor's have had success with HC, have banned the use of the drug for treatment of Covid. The problem is, I have never heard you or any others make a public correction or issue an apology about these bogus studies. I certainly have to wonder why. Why not issue a public statement to clear the air and once again allow it's use if the Doctor feels it is best for their patient. As It stands now, there is complete confusion on the matter. I am sure there are many people who still think it is way too dangerous. That it will kill you, as some have stated. Unbelievable!

When it comes to the concerns I have heard you and others express about the heart rhythm side affect of HC. I am not a doctor, but I have heard several Doctors dispute that. Doctors who prescribe HC for arthritis, lupus, and maybe other off label uses. They have said that in their situations, they have only seen limited side affects with using the drug. Some stated they used to do the heart testing with patients, but no longer feel it is necessary because it is practically non-existent in heart healthy patients. I have heard some using HC for Covid who are testing the heart because of the concerns even though this drug has been used for decades, with a well known track record.

Dr. Hahn, I do thank you for your service to our country. I am sorry for being rather harsh in my statements. I just feel so passionate about this. I do personally feel that lives have been and will be lost needlessly because of the negative connotation that has been placed on HC. Not only by the FDA and other officials, our news media, but even by many in the medical community. I am convinced that a lot has to do with political bias. To put that bias ahead of saving lives is beyond anything I can imagine. I heard one Doctor state that some in the medical community have broken their oath as a Doctor, to put the health and wellbeing of their patients first. That it is a derelict of duty.

I pray that someone would step forward and set the record straight, so more lives can be saved with allowing the use of HC and these other drugs.

Thank you and "God Bless",
(b) (6) (a concerned citizen from (b) (6)

Sent from my iPad

On Aug 7, 2020, at 2:01 PM, CDER DRUG INFO <DRUGINFO@fda.hhs.gov> wrote:

Dear (b) (6)

Thank you for writing Dr. Stephen M. Hahn, Commissioner of the Food and Drug Administration (FDA). Your email was forwarded to the Division of Drug Information, in the FDA's Center for Drug Evaluation and Research (CDER) for a response. Due to the number of COVID-19 related inquires we have received, we apologize for the delay in responding.

The decision to revoke the Emergency Use Authorization (EUA) for chloroquine and hydroxychloroquine was based on clinical trial results and data, which are found in the Memorandum Explaining Basis for Revocation of EUA. This document describes the studies that were reviewed and how FDA utilized the data in decision making.

We hope you found this information helpful.

Best regards,

Joy
Pharmacist
Division of Drug Information
Center for Drug Evaluation and Research
Tel: 855-543-DRUG (855-543-3784)
druginfo@fda.hhs.gov

Follow us
<image001.jpg>

<image002.jpg>

<image003.jpg>

<image004.png>

Sent: 6/12/2020 6:31:29 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Hi Liz,

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 6:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

This is the revocation letter for the hydroxy/chloroquine EUA. (b) (5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 5:46 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks, Liz. For anyone who has not yet viewed this, I have added my revision to the footnote to the version Liz provided in the attached. (If you have already marked up the previous version, you can send me that.)

Please let me know if you have any comments or if you will not have comments, I guess at least by tomorrow morning. Liz and Andrew, who else will need to review this before it is finalized for signature on Monday?

Andrew, do you have a sense of when you might have the memo to be enclosed ready for review?

Don << File: Hydroxy revocation db 4 40.doc >>

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 4:27 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks Don- I made a couple of small edits for consistency (b) (5) throughout. Thanks.
<< File: Hydroxy revocation db.doc >>

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 4:08 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Please use this version (revised footnote). Thanks. << File: Hydroxy revocation db.doc >>

From: Beers, Donald
Sent: Friday, June 12, 2020 4:04 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Liz,

Thanks for putting this together. In the attached I have suggested some edits. Let me know what you think.

Don << File: Hydroxy revocation db.doc >>

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 12:07 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Attached is a simple draft. (b) (5) [redacted] Thanks.
<< File: Hydroxy revocation.doc >>

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 11:51 AM
To: Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

FYI
<< File: BARDA EUA 039 Withdrawal Letter FINAL.docx >>

From: Beers, Donald
Sent: Friday, June 12, 2020 11:44 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

(b) (5) [redacted]

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, June 12, 2020 11:36 AM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

(b) (6) just called me. They need our comments asap, so that they can finalize the memo and send back to us, to be forwarded to Commissioner Hahn.
Patrizia

From: (b) (6) [redacted]
Sent: Friday, June 12, 2020 11:33 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Disbrow, Gary (OS) (b) (6) [redacted]
Subject: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Patrizia, John and Don,

Please see our revised final draft. Comments or suggested edits are welcome.

(b) (6)

<< File: BARDA EUA 039 Withdrawal Letter FINAL.docx >>

(b) (6) [redacted]
Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: 202-260-0899
Mobile: (b) (6) [redacted]
Fax: 202-205-0873
email: (b) (6) [redacted]

From: Sadove, Elizabeth [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FD45C627000D4F34B9DB362FF2B6AF4B-SADOVEE]
Sent: 6/12/2020 6:51:57 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Date: June 12, 2020 at 6:40:39 PM EDT
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thank you, Liz. (b) (5)

Best,
Denise

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 6:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

This is the revocation letter for the hydroxy/chloroquine EUA. (b) (5)

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 5:46 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks, Liz. For anyone who has not yet viewed this, I have added my revision to the footnote to the version Liz provided in the attached. (If you have already marked up the previous version, you can send me that.)

Please let me know if you have any comments or if you will not have comments, I guess at least by tomorrow morning. Liz and Andrew, who else will need to review this before it is finalized for signature on Monday?

Andrew, do you have a sense of when you might have the memo to be enclosed ready for review?

Don << File: Hydroxy revocation db 4 40.doc >>

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

Sent: Friday, June 12, 2020 4:27 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks Don- I made a couple of small edits for consistency (b) (5) throughout. Thanks.
<< File: Hydroxy revocation db.doc >>

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 4:08 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Please use this version (revised footnote). Thanks. << File: Hydroxy revocation db.doc >>

From: Beers, Donald
Sent: Friday, June 12, 2020 4:04 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Liz,

Thanks for putting this together. In the attached I have suggested some edits. Let me know what you think.

Don << File: Hydroxy revocation db.doc >>

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 12:07 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Attached is a simple draft. (b) (5)

Thanks.
<< File: Hydroxy revocation.doc >>

From: Beers, Donald <Donald.Beers@fda.hhs.gov>

Sent: Friday, June 12, 2020 11:51 AM
To: Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

FYI
<< File: BARDA EUA 039 Withdrawal Letter FINAL.docx >>

From: Beers, Donald
Sent: Friday, June 12, 2020 11:44 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

(b) (5)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, June 12, 2020 11:36 AM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

(b) (6) just called me. They need our comments asap, so that they can finalize the memo and send back to us, to be forwarded to Commissioner Hahn.
Patrizia

From: (b) (6)
Sent: Friday, June 12, 2020 11:33 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: (b) (6)
Subject: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Patrizia, John and Don,

Please see our revised final draft. Comments or suggested edits are welcome.

(b) (6)

<< File: BARDA EUA 039 Withdrawal Letter FINAL.docx >>

(b) (6)
Deputy Assistant Secretary
Director, Medical Countermeasure Programs

Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: 202-260-0899
Mobile: (b) (6)
Fax: 202-205-0873
email: (b) (6)

Sent: 6/12/2020 6:34:13 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thank you for sending in advance for review. I will see if Anand needs to review.

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 6:29 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

This is the revocation letter for the hydroxy/chloroquine EUA. It's readying for clearance, with the goal of signing Monday morning. Does anyone else in OC (e.g., Anand, Anna) need to review?

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 5:46 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks, Liz. For anyone who has not yet viewed this, I have added my revision to the footnote to the version Liz provided in the attached. (If you have already marked up the previous version, you can send me that.)

Please let me know if you have any comments or if you will not have comments, I guess at least by tomorrow morning. Liz and Andrew, who else will need to review this before it is finalized for signature on Monday?

Andrew, do you have a sense of when you might have the memo to be enclosed ready for review?

Don << File: Hydroxy revocation db 4 40.doc >>

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 4:27 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Thanks Don- I made a couple of small edits for consistency (b) (5) throughout. Thanks.
<< File: Hydroxy revocation db.doc >>

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 4:08 PM

To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Please use this version (revised footnote). Thanks. << File: Hydroxy revocation db.doc >>

From: Beers, Donald
Sent: Friday, June 12, 2020 4:04 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Liz,

Thanks for putting this together. In the attached I have suggested some edits. Let me know what you think.

Don << File: Hydroxy revocation db.doc >>

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Friday, June 12, 2020 12:07 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Attached is a simple draft. (b) (5) [redacted]. Thanks.
<< File: Hydroxy revocation.doc >>

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Friday, June 12, 2020 11:51 AM
To: Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

FYI
<< File: BARDA EUA 039 Withdrawal Letter FINAL.docx >>

From: Beers, Donald
Sent: Friday, June 12, 2020 11:44 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sipes, Grail

<Grail.Sipes@fda.hhs.gov>
Subject: RE: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

(b) (5)

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, June 12, 2020 11:36 AM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Sipes, Grail <Grail.Sipes@fda.hhs.gov>
Subject: FW: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

(b) (6) ust called me. They need our comments asap, so that they can finalize the memo and send back to us, to be forwarded to Commissioner Hahn.
Patrizia

From: (b) (6)
Sent: Friday, June 12, 2020 11:33 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: (b) (6)
Subject: FOUO INFORMATION NOT RELEASABLE UNDER FOIA

Patrizia, John and Don,

Please see our revised final draft. Comments or suggested edits are welcome.

(b) (6)

<< File: BARDA EUA 039 Withdrawal Letter FINAL.docx >>

(b) (6)
Deputy Assistant Secretary
Director, Medical Countermeasure Programs
Biomedical Advanced Research and Development Authority
BARDA
Assistant Secretary for Preparedness and Response ASPR
Department of Health and Human Services
330 Independence Avenue, S.W. Room 640 G
Washington, D.C. 20201
Office: 202-260-0899
Mobile: (b) (6)
Fax: 202-205-0873
email: (b) (6)

prohibited. If you have received this transmission in error, please immediately notify the sender and destroy the original transmission, attachments, and destroy any hard copies.

Note to contractors: nothing in this e-mail is intended to constitute contractual direction or to impact cost, price, or schedule contained in the contract. If the contractor believes there is an impact, the contractor must disregard that portion of the communication and contact the Contracting Officer for direction

From: Mair, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F4511BDAD7564D7FAC7EADC7961467AB-MICHAEL.MAI]
Sent: 6/8/2020 12:57:22 PM
To: Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: does the Commish know

About the HCQ/CQ EUA revocation?

From: Emery, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C68B7BBB994D48FDB2F6F6802BFDB605-JOHN.EMERY]
Sent: 6/25/2020 1:06:34 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Dickinson, Elizabeth (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=05cb143d66ed470ebe4dba5c54a88074-EDickins]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Kempic, Annamarie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9cb9e4f9d4d4e6382380a216e50a99c-AKempic]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Williams, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63c605573234410491fad54cde597ecd-Susan.Willi]; Hong, Samantha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9bf5fc8a16d344729f02478016a3469d-Samantha.Ho]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]; Birnkrant, Debra B [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=07e740904c9042a0b99c6ddc16550b08-BIRNKRANT]; Schumann, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e4251f58ae47b195422a2349b5e3ce-SCHUMANNK]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Booze, Kristen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86338261bf6646c59bf8cf7c18d12de3-Kristen.Boo]; Corrigan-Curay, Jacqueline [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cff7c455d5d24bc69c1239a23041a596-Jacqu.Corri]; Gormley, Andrea (Vincent) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a3bcfc81bde2490abfb3b4180df23918-VINCENTA]; Leissa, Brad G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=79e04d8b4cdf4ac7a9e823c966eef5c2-LEISSAB]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Hodowanec, Aimee [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a4ec98d46a47e7847a33f14b1ee4f8-Aimee.Hodow]; Singer, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dceb8503eea54637923bdcaec04e4349-SINGERM]; Ashley, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=40241a76230349cbb195ab1721092196-Donald.Ashl]; Leboeuf, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d35ec585598148118abdfd25f495c8f5-Andrew.Lebo]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Fan, Jianghong [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=54b7399df3ea4787b5763c231ae7fbd3-Jianghong.F]; Zheng, Nan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=841ac2bd98db4e21a610031444394f74-Nan.Zheng]; Zhang, Xinyuan

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=126c81b1a5804e00bb58ee32cec1a0b9-ZHANGX]; Arya, Vikram [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7d1c11aca00f4309bdff17585c28a16b-ARYAV]; Swank, Kimberley [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e628b3cb89fd43a6b6a6e62feab03a5f-Kimberley.S]; McCartan, Kate [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=06133f58c9514566b51e14c43c463619-Kate.McCart]; Kapoor, Rachna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43a5103afc8c4c03aaad09d3bc9d25e0-KAPOORR]; Gada, Neha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a9d0cda311464b76b35d23707fa0afec-GADAN]; Diak, Ida-Lina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cc86c49867a84b549f1bfcb35507c7e6-DIAKI]; Pratt, Natasha [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1bed8e9f9cb140348d376c67f9966ba2-CHENCH]; Falconer, Monique [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0f07eac8afa8470cad2aaa63d5acb73a-FALCONERM]; Buhse, Lucinda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=03c54017a02447e1aea701cbe7c11aab-BUHSEL]; Liu, Qi (CDER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=631d5e6ef4374a05976bc3d0a16f1e30-liuq]; Bergman, Kimberly [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e8c7d96490364402908eda50066c557b-BERGMANK]; Zheng, Jenny H. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0a2425c4f44c44ec8a6a935b1daa8578-ZHENGJE]; Reynolds, Kellie S [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86906735a6284de08cefdab86da6fa99-REYNOLDSK]

CC: Lee, Marguerite [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e40a857adef4a7587b71992d79809e0-Marguerite.]; Wanke, Hilary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3595b19b65eb4cdcb19e5c4f7dc11706-Hilary.Wank]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Litigation Hold [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae774ddb5d84977aac503990e4b3710-Litigation]; OP Policy Review Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=880566a7249e4495973f6957997d7031-OP Policy R]

Subject: ACTION REQUIRED: Retention of records relating to EUA for HCQ/CCQ

Importance: High

All:

Please be advised that a lawsuit has been filed in the United States District Court for the Western District of Michigan challenging the now-revoked emergency use authorization (EUA) for hydroxychloroquine sulfate and chloroquine phosphate (HCQ/CQ). The suit was filed by the Association of American Physicians and Surgeons against FDA, Commissioner Hahn, the Biomedical Advanced Research and Development Authority (BARDA), Acting Director Disbrow, the Department of Health and Human Services, and Secretary Azar. The Plaintiff makes allegations about the circumstances surrounding the issuance and revocation of the EUA and the HCQ in the Strategic National Stockpile (SNS). Plaintiff asks the court to order the Defendants to distribute HCQ from the stockpile promptly to members of the public who have valid prescriptions and to enjoin the Defendants from placing any restrictions on HCQ .

While this litigation is pending, the agency is under an obligation to retain documents and communications, including emails and other electronically stored information, that are potentially relevant to the case. Such documents and communications include, but are not limited to:

Documents, electronically stored information, and tangible items that were considered, directly or indirectly, during the decision-making process in connection with the request for and issuance of the EUA, the request for and revocation of the EUA, the donation of HCQ to the SNS, and the disposition of HCQ from the SNS after the EUA was revoked.

During the course of any lawsuit, the opposing party may use the discovery process to obtain agency records about the allegations related to the case. The law requires FDA to preserve such information in whatever form it is generated and maintained. Therefore, the agency requires your assistance to preserve documents and other evidence, including electronic data, in connection with the subject of these lawsuits.

As an FDA employee, you are required to preserve all documents and data related to the subject of these lawsuits, including information stored in hard copy, on computer systems, on removable or portable electronic storage media, and on your personal computer, if used to create agency records. All electronically stored data, including e-mails and other electronic communication, word processing documents, spreadsheets, databases, calendars, telephone voice mails, and other kinds of media, must be retained until resolution of this matter. In addition, you must retain non-electronic documents and evidence in whatever form, including personal or desk files, calendars, notes, correspondence, and other things relevant to the case. Any routine data destruction policies related to these records must be discontinued until further notice from me.

You do not need to collect and produce the documents/electronic data at this time; rather, we are only seeking to preserve and prevent the destruction of existing information. Failure to preserve and retain information may result in sanctions against the agency. Consequently, if you are unsure whether certain information should be preserved, err on the side of caution and preserve the information until you have discussed the issue with [indicate who should be contacted]. If production of some or all of the material is required at a later date, you will receive further instructions from an attorney assigned to this matter. Also, if you have any questions about how to preserve electronically stored information, please contact me.

Although you are not required to collect documents/electronic data at this time, where possible, it is advisable to segregate potentially relevant information. This can help ensure it is not inadvertently destroyed (e.g., by operation of an electronic system or according to prior record retention policies) and can facilitate ease of retrieval if production becomes necessary.

In addition, please make sure that this message is distributed to all personnel in your office who may be involved in, or have information pertaining to, this lawsuit. Because this message is confidential, however, do not send it outside the agency without first discussing it with me or an attorney from my office. **Please send me the names of the people to whom you forward this message**. I also advise that you document the specific actions taken by you and your office in response to this message.

If you or your office have in your possession, custody, or control any documents/electronic data within the category described above, or if you are responsible for an office that has any documents/electronic data, you must preserve and retain the information through the time that you are either instructed to collect it or informed that the preservation instruction is no longer in effect. As stated above, no documents/electronic data need be collected or produced at this point.

Please click the "yes" voting button above to confirm that you have received this notice, understand your obligations, and agree to comply with the instructions.

If you have any questions about your obligations to preserve information, please contact me at 240-381-3334 or email me at john.emery@fda.hhs.gov.

John "Mac" Emery
Paralegal Specialist

Office of Chief Counsel
Cell: 240-381-3334

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 6/17/2020 7:49:09 AM
To: 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: 10:00 JIC notes
Attachments: 20200617_JICMeetingNotes.docx

JIC daily check-in M-F, 10:00 – 10:30 a.m. **WebEx only**. For first part of meeting, we will run down status of current items, then focus on hot topics, if any. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

Reminders/notes/resources:

- Please ask, "Who else needs to know?" (remember to use JIC email lists, in case people are on leave - "Which email do I use?" is included in the Welcome to JIC file)
- Major study finds common steroid reduces deaths among patients with severe Covid-19 (STAT, referring to dexamethasone)

TODAY'S FOCUS DISCUSSION (Second half of meeting)

- Hot topics for the group
  - From NICCL call - HHS will issue a press release on distribution of remdesivir Saturday morning

Pending, from previous discussions:

- **ACTION: teams will review their evergreen content, including evergreen tweets, for continued relevance/appropriateness of use, and we'll discuss w/new ideas on Thursday June 18**

Press/Media Engagements:

- What is Dr. Hahn up to today
- White House (TPs, when needed: Michael F.)

Then, by area:

- Press releases/media/WHTF
- CDRH
- CDER
- CBER
- CFSAN
- CVM
- ORA
- OPLIA
- CTP
- OCC
- OL
- Consumer
- Stakeholder
- Web
- Social
- Internal
- Meeting report-outs

SITREP

Published today, June 17

- Press statements:
  - Daily roundup on topics including … [add input]
  - …
- Dr. Hahn media:
  - …
- Emergency Use Authorizations:
  - …
- Web updates:
  - …
- Stakeholders:
  - MCMi weekly email update (PDF) ++LINK
- Consumers & patients:
  - …
- Internal
  - …

Likely today, June 17 [all internal confidential]

- Press statements:
  - FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Placing Public Health at Risk [SP link] (first WL issued 6/10, but not yet posted - Medakit Ltd.; 4 WLs in this release) ~6/17
  - FDA quote in partner release (FDA-funded): C-Path Launches CURE Drug Repurposing Collaboratory to Accelerate Identification of Existing Drugs to Treat Infectious Diseases, Including COVID-19 + will be added to innovation web page - [SP link] likely ~6/17 (delayed for revisions/another OCC review)
  - …
- Emergency Use Authorizations:
  - …
- Web updates:
  - Main FAQ edits/updates from CDER [SP link]
  - …
- Stakeholders:
  - OEA: Stakeholder toolkit for Convalescent Plasma, including fact sheet, tweets, and newsletter content (some materials in toolkit now available in Spanish) - likely ~6/17
  - CFSAN: Foods program calls with states, to raise particular issues/challenges the industry is experiencing and to identify potential solutions - calls to begin 6/17 [SP link - slides]
  - …
- Consumers & patients:
  - Weekly consumer update FAQ email, on COVID-19 treatments, and proper use of disinfectants [SP link]
- Internal
  - …

Likely tomorrow, June 18 [all internal confidential]

- Press statements:
  - Daily roundup
  - FDA Takes Additional Action to Harness Real-World Data to Inform COVID-19 Response Efforts [SP link] + FDA quote in Reagan-Udall Foundation release [SP link] - 6/18, ~10:00 a.m.
  - …
- Dr. Hahn media:
  - …
- Emergency Use Authorizations:

- ...
- Web updates:
  - ...
- Stakeholders:
  - CDER: CURE ID discussion at International Society for Neglected Tropical Diseases webinar – Heather Stone (OMP) [slides] 6/18
  - CDER: MedDRA User's Group webinar: Impact of COVID-19 on pharmacovigilance, Sonja Brajovic (OSE) – 6/18
  - SES: Dr. Hahn to provide opening remarks on call with American Hospital Association (membership meeting about 700 members) - 6/18
- Consumers & patients:
  - ...
- Internal
  - ...

Pending release, week of June 15 and beyond [all internal confidential]

- Press statements:
  - Daily roundups (M-F)
  - Inspection-related updates:
    - Foreign inspections with update on drug UFAs ~ week of 6/15
    - Foods interim update based on AFDO response, focus on food safety going into summer season - maybe week of 6/15
    - Domestic inspections update—as we have more clarity around resuming domestic inspections, will provide - timing TBD (longer term)
- Dr. Hahn media:
  - Twitter Q&A initiative responses [SP link]
- CDRH:
  - Upcoming IIE guidances:
    - CDRH: Update to 506J guidance on device shortage reporting ~ 6/18 or 6/19
  - EUAs:
    - ...
  - Web updates:
    - WLs - Operation Fraud Alert - fraudulent COVID products (CDRH, Jeremy Kahn)~mid June or later
  - Stakeholders:
    - CDRH: Communications to alert HCPs on Certain COVID-19 Serology/Antibody Tests Should Not Be Used (scope broadened beyond Phamatech) ~later week of 6/15, or week of 6/22
    - CDRH: New FAQ web page - Importing (+ Registration and Listing) Medical Devices During the COVID-19 Pandemic [SP link] ~later week of 6/15, or week of 6/22
    - CDRH: Webinar series on PPE (imported respirators) – next 6/23 (comms likely ~ 6/17)
  - *Beyond this week:*
    - IIE guidances:
      - Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency ~week of 6/22 or later
      - Recalls of Medical Devices and Corrective Actions/Repairs of Electronic Products During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/22 or later
      - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications – week of 6/22 or later
      - Enforcement Policy for Non-invasive Electrical Stimulation Devices Intended for Treatment of Major Depressive Disorder (MDD) – week of 6/22 or later
      - Enforcement Policy for Digital Health and Stimulation Therapeutic Devices for Physical Rehabilitation – week of 7/5 or later

- Enforcement Policy for Coagulation Systems for Measurement of Viscoelastic Properties During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – timing TBD
- EUAs:
- Becton, Dickinson and Company, Veritor SARS-CoV-2 Assay
- Spectrum Solutions LLC, SDNA-1000 Saliva Collection Device
- Fulgent/Picture Genetics; Nasal swab home collection kit - timing TBD
- Rapid Rona home collection kit using Hologic's Panther Fusion COVID-19 EUA assay - timing TBD
- Additions to umbrella EUAs for various devices, ventilators, and support accessories

- CDER:
  - Stakeholders:
    - CDER guidance: Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency (+Daily Roundup, listserv messages [SP link]) - likely week of 6/15, later in week (in OMB clearance)
  - *Beyond this week:*
    - Guidance: COVID-19 infection in Employees in Pharmaceutical Manufacturing (+Daily Roundup, listserv, reactive QAs) – late June
    - Guidance: Manufacturing, Supply Chain, and Drug Inspections During COVID-19 Public Health Emergency - Questions and Answers (+Daily Roundup) – late June
    - Health Affairs Blog: CDER's Contributions Towards Protecting Public Health During the COVID-19 Pandemic By Patrizia Cavazzoni, M.D. [SP link] - June/July
- CBER:
  - Use of stem cells (comms and target date TBD)
  - Updates on HCT/Ps - late week of 6/15, or week of 6/22
  - Guidance on vaccines - timing TBD
- CFSAN:
  - Checklist (w/CVM): Employee Health and Food Safety Checklist for Human and Animal Food Operations During COVID-19 [SP link] mid-to-late June. Needs to go through HHS, OMB clearance after CDC posts testing guidance (which is also in clearance)
  - Working to clear a reactive statement RE: the salmon and cutting boards story out of China 6/16
- CVM:
  - ...
- ORA:
  - Guidance: Disinfection of Surfaces on Interstate Conveyances (in OMB clearance)
- OPLIA:
  - Potentially a new blog by Europe office, emphasizing EU collaboration - week of 6/22 or later
  - Feature on ORA employee's experience being in India during pandemic and visiting hydroxychloroquine plant - possible FDA Voices - TBD on external comms
- CTP:
  - ...
- Consumer & patient updates:
  - Language translation of FAQs on face coverings and for DIY ventilator makers
  - Getting Smarter About Food Safety: The Pandemic and Lessons Learned (based on similar FDA Voices) ~week of 6/15
- Web updates:
  - OC/CDRH: User-friendly tool on website for labs that need information on test component substitutes when supply issues arise (+ webinar)
  - OCET: New page: Updates on activities performed under the rapid response to COVID-19 3D printing MOU (w/NIH, VA) [SP link - markup; SP link for OCC clearance] maybe ~6/18 or 6/19
  - At-a-Glance PDF update 6/19
- Stakeholders:
  - CDER: Virtual/remote human factor validation testing follow-up (internal reactive Q&A)

- RADM Araojo presenting (via pre-recorded video) on Under-representation in Clinical Trials and the Implications for Drug Development, AACR Virtual Annual Meeting II, including highlighting FDA OMHHE's ongoing efforts in response to COVID-19 [SP link - talking points] 6/22

- Internal:
  - Updated Occupational Health employee QAs for InsideFDA in clearance (w/OO)
  - Working on new employee QAs on workplace reopening; in development
  - Updates to Occupational Health InsideFDA page, including updated clinic visit questionnaire [SP link] and new social distancing flier for internal use
  - InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [SP link] - holding for reopening FDA plan

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, and other social media (e.g., Facebook, LinkedIn)
- Daily or as needed - updated PDFs listing EUAs for therapeutics and medical devices
- 2x/ weekly (Wed & Fri): COVID-19 response recap emails to stakeholders
- Weekly (Wed) - Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
- Weekly (Wed): Coronavirus Q&As for Consumers – top Q&A of week email to Consumer Update list
- Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA, and responding to questions received from HHS employee portal

Published yesterday, June 16

- Press statements:
  - Daily roundup on topics including web FAQ updates on a new medical device adverse event reporting web page, a serology test EUA revocation, updated templates for developers that intend their assay to be used for pooling patient samples or for screening asymptomatic individuals, and a testing update
  - FDA Revokes Emergency Use Authorization for Chembio Antibody Test
  - Facilitating Diagnostic Test Availability for Asymptomatic Testing and Sample Pooling (w/CDRH web updates)
- Emergency Use Authorizations:
  - Technical Safety Services LLC; Technical Safety Services VHP Decontamination System (~6/13)
  - Oceanetics, Inc.; Negative-pressure Respiratory System with Advanced Ventilation Return (NRSAVR-100) (~6/13)
  - Kaiser Permanente Mid-Atlantic States; KPMAS COVID-19 Test (molecular; home collection kit)
  - Applied BioCode Inc.; BioCode SARS-CoV-2 Assay (molecular)
  - Emory Medical Laboratories, Emory University Hospital; SARS-CoV-2 RBD IgG (serological)
  - EUA revocation: Chembio Diagnostic System, Inc.; DPP COVID-19 IgM/IgG System - revocation letter
- Web updates:
  - CDRH: Asymptomatic Testing Updates to testing FAQ, updated molecular diagnostic EUA templates
  - EUA archive page updates: device EUAs, all archived EUAs
- Stakeholders:
  - CDER: Drug Information Association (DIA) 2020 Virtual Global Annual Meeting: Regulatory Agility Under COVID 19 - Jeannie David (DSS)

SITREP ENDS

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- NICCL calls (Tu/Th 10:15 a.m.)

MEDIA MONITORING

- See daily a.m. JIC email from Andrea Takash
- See NICCL JIC folder for social listening and other reports

###

April Finnen
IMG JIC Section Chief
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)
U.S. Food and Drug Administration
Cell: 240-507-7742 ←Call this # or IM/Skype to reach me
Email: april.finnen@fda.hhs.gov
JIC (Joint Information Center) leads email: 2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov

Agenda and notes – JIC 10:00 a.m. check-in

June 17, 2020

JIC daily check-in M-F, 10:00 – 10:30 a.m. **WebEx only**. For first part of meeting, we will run down status of current items, then focus on hot topics, if any. After the meeting, updated notes will be available in SharePoint (JIC [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/default.aspx?RootFolder=%2Forgs%2FOC%2DOCET%2FOCETdocs%2FnCoV%2FShared%20Documents%2FJIC%20%2D%20FDA%20IMG%2FMeeting%20notes&FolderCTID=0x012000A3A7A055F609174BBA12CCD50BB2BD50&View=%7bAA5D576D-A152-4B9E-B345-979F92F9C4C9%7d"]).

Reminders/notes/resources:

- Please ask, "Who else needs to know?" (remember to use JIC email lists, in case people are on leave - "Which email do I use?" is included in the [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/20200603_WelcomeToJIC.pdf"])
- [HYPERLINK "https://www.statnews.com/2020/06/16/major-study-finds-common-steroid-reduces-deaths-among-patients-with-severe-covid-19/"] (STAT, referring to dexamethasone)

TODAY'S FOCUS DISCUSSION (Second half of meeting)

- Hot topics for the group
  - From NICCL call - HHS will issue a press release on distribution of remdesivir Saturday morning

Pending, from previous discussions:

- **ACTION: teams will review their evergreen content, including** [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Social%20media/Evergreen%20Tweet%20Repository%20Approved%204.17.20.docx"]**, for continued relevance/appropriateness of use, and we'll discuss w/new ideas on Thursday June 18**

Press/Media Engagements:

- What is Dr. Hahn up to today
- White House (TPs, when needed: Michael F.)

Then, by area:

- Press releases/media/WHTF
- CDRH
- CDER
- CBER
- CFSAN
- CVM
- ORA
- OPLIA
- CTP
- OCC
- OL
- Consumer

- Stakeholder
- Web
- Social
- Internal
- Meeting report-outs

SITREP

Published today, June 17

- Press statements:
  - Daily roundup on topics including … [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/2020.06.17.docx"]]
  - …
- Dr. Hahn media:
  - …
- Emergency Use Authorizations:
  - …
- Web updates:
  - …
- Stakeholders:
  - MCMi weekly email update (PDF) ++LINK
- Consumers & patients:
  - …
- Internal
  - …

Likely today, June 17 [all internal confidential]

- Press statements:
  - FDA Issues Warning Letters to Companies Inappropriately Marketing Antibody Tests, Placing Public Health at Risk [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/20200612%20-%20Test%20Warning%20Letters%20Press%20Release%20Draft%20v2.docx"]] (first WL issued 6/10, but not yet posted - Medakit Ltd.; 4 WLs in this release) ~6/17
  - FDA quote in partner release (FDA-funded): C-Path Launches CURE Drug Repurposing Collaboratory to Accelerate Identification of Existing Drugs to Treat Infectious Diseases, Including COVID-19 + will be added to [HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/innovation-respond-covid-19"] web page - [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/CURE_PPP-Draft_PressRelease-6%208%2020.docx"]] likely ~6/17 (delayed for revisions/another OCC review)
  - …
- Emergency Use Authorizations:
  - …

- Web updates:
  - Main FAQ edits/updates from CDER [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Web/For%20clearance/General%20FAQs/20200616_FAQ_CDER_Updates.docx"]]
  - ...
- Stakeholders:
  - OEA: Stakeholder toolkit for Convalescent Plasma, including fact sheet, tweets, and newsletter content (some materials in toolkit now available in Spanish) - likely ~6/17
  - CFSAN: Foods program calls with states, to raise particular issues/challenges the industry is experiencing and to identify potential solutions - calls to begin 6/17 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OFVM/OFVMExecSec/OEPReview/Shared%20Documents/COVID-19/Industry%20info/Processed%20Fruit%20%20Veg%20Industry%20Request%2006122020.pptx"] - slides]
  - ...
- Consumers & patients:
  - Weekly consumer update FAQ email, on COVID-19 treatments, and proper use of disinfectants [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Consumer/20200616FAQemail.docx"]]
- Internal
  - ...

Likely tomorrow, June 18 [all internal confidential]

- Press statements:
  - Daily roundup
  - FDA Takes Additional Action to Harness Real-World Data to Inform COVID-19 Response Efforts [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/Diagnostics%20Accelerator%20PR%206%2015%2020.docx"]] + FDA quote in Reagan-Udall Foundation release [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/Diagnostics%20Evidence%20Accelerator%20RUF%20Draft%206%2015%2020.docx"]] - 6/18, ~10:00 a.m.
  - ...
- Dr. Hahn media:
  - ...
- Emergency Use Authorizations:
  - ...
- Web updates:
  - ...
- Stakeholders:
  - CDER: CURE ID discussion at International Society for Neglected Tropical Diseases [HYPERLINK "https://www.isntd.org/isntd-connect"]– Heather Stone (OMP) [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDER/CURE_ISNTD%20Webinar_6.16.2020.pptx"]] 6/18

- CDER: MedDRA User's Group webinar: Impact of COVID-19 on pharmacovigilance, Sonja Brajovic (OSE) – 6/18
- SES: Dr. Hahn to provide opening remarks on call with American Hospital Association (membership meeting about 700 members) - 6/18

- Consumers & patients:
  - ...
- Internal
  - ...

***Pending release, week of June 15 and beyond** [all internal confidential]*

- Press statements:
  - Daily roundups (M-F)
  - Inspection-related updates:
    - Foreign inspections with update on drug UFAs ~ week of 6/15
    - Foods interim update based on AFDO response, focus on food safety going into summer season - maybe week of 6/15
    - Domestic inspections update—as we have more clarity around resuming domestic inspections, will provide - timing TBD (longer term)
- Dr. Hahn media:
  - Twitter Q&A initiative responses [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Social%20media/20200615Twitter%20QA%20Ep2%20v2.docx"]]
- CDRH:
  - Upcoming IIE guidances:
    - CDRH: Update to 506J guidance on device shortage reporting ~ 6/18 or 6/19
  - EUAs:
    - ...
  - Web updates:
    - WLs - Operation Fraud Alert - fraudulent COVID products (CDRH, Jeremy Kahn)~mid June or later
  - Stakeholders:
    - CDRH: Communications to alert HCPs on Certain COVID-19 Serology/Antibody Tests Should Not Be Used (scope broadened beyond Phamatech) ~later week of 6/15, or week of 6/22
    - CDRH: New FAQ web page - Importing (+ Registration and Listing) Medical Devices During the COVID-19 Pandemic [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDRH/20200603%20COVID-19%20FAQ%20IMPORTS%20clean%20final%20OPEQ%20cleared%20edits%20from%20DICE.docx"]] ~later week of 6/15, or week of 6/22
    - CDRH: Webinar series on PPE (imported respirators) – next 6/23 (comms likely ~ 6/17)
  - *Beyond this week:*
    - IIE guidances:
      - Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency ~week of 6/22 or later

        - Recalls of Medical Devices and Corrective Actions/Repairs of Electronic Products During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/22 or later
        - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications – week of 6/22 or later
        - Enforcement Policy for Non-invasive Electrical Stimulation Devices Intended for Treatment of Major Depressive Disorder (MDD) – week of 6/22 or later
        - Enforcement Policy for Digital Health and Stimulation Therapeutic Devices for Physical Rehabilitation – week of 7/5 or later
        - Enforcement Policy for Coagulation Systems for Measurement of Viscoelastic Properties During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – timing TBD
    - EUAs:
        - Becton, Dickinson and Company, Veritor SARS-CoV-2 Assay
        - Spectrum Solutions LLC, SDNA-1000 Saliva Collection Device
        - Fulgent/Picture Genetics; Nasal swab home collection kit - timing TBD
        - Rapid Rona home collection kit using Hologic's Panther Fusion COVID-19 EUA assay - timing TBD
        - Additions to umbrella EUAs for various devices, ventilators, and support accessories
- CDER:
    - Stakeholders:
        - CDER guidance: Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency (+Daily Roundup, listserv messages [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDER/StatsCovid19GuidanceDraftEmailsJune15.docx"]]) - likely week of 6/15, later in week (in OMB clearance)
    - *Beyond this week:*
        - Guidance: COVID-19 infection in Employees in Pharmaceutical Manufacturing (+Daily Roundup, listserv, reactive QAs) – late June
        - Guidance: Manufacturing, Supply Chain, and Drug Inspections During COVID-19 Public Health Emergency - Questions and Answers (+Daily Roundup) – late June
        - Health Affairs Blog: CDER's Contributions Towards Protecting Public Health During the COVID-19 Pandemic By Patrizia Cavazzoni, M.D. [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDER/HACDERWorkCovid19PandemicJune4.docx"]] - June/July
- CBER:
    - Use of stem cells (comms and target date TBD)
    - Updates on HCT/Ps - late week of 6/15, or week of 6/22
    - Guidance on vaccines - timing TBD
- CFSAN:
    - Checklist (w/CVM): Employee Health and Food Safety Checklist for Human and Animal Food Operations During COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OFVM/OFVM%20landing%20page/Cross_Cutting_Issues/Shared%20Documents/FSMA%202019-2020/FSMA%20and%20COVID-19/Employee%20Health%20Food%20Safety%20-Checklist-for-reopening-and-operation-

changes%20515TS.docx"]] mid-to-late June. Needs to go through HHS, OMB clearance after CDC posts testing guidance (which is also in clearance)
    - Working to clear a reactive statement RE: the salmon and cutting boards story out of China 6/16
- CVM:
    - ...
- ORA:
    - Guidance: Disinfection of Surfaces on Interstate Conveyances (in OMB clearance)
- OPLIA:
    - Potentially a new blog by Europe office, emphasizing EU collaboration - week of 6/22 or later
    - Feature on ORA employee's experience being in India during pandemic and visiting hydroxychloroquine plant - possible FDA Voices - TBD on external comms
- CTP:
    - ...
- Consumer & patient updates:
    - Language translation of FAQs on face coverings and for DIY ventilator makers
    - Getting Smarter About Food Safety: The Pandemic and Lessons Learned (based on similar FDA Voices) ~week of 6/15
- Web updates:
    - OC/CDRH: User-friendly tool on website for labs that need information on test component substitutes when supply issues arise (+ webinar)
    - OCET: New page: Updates on activities performed under the rapid response to COVID-19 3D printing [HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/fda-efforts-connect-manufacturers-and-health-care-entities-fda-department-veterans-affairs-national"] (w/NIH, VA) [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDRH/20200522_3DprintMOU_update.docx"] - markup; [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Web/For%20clearance/20200612_3DprintMOU_update_OCCreview.docx"]] maybe ~6/18 or 6/19
    - At-a-Glance PDF update 6/19
- Stakeholders:
    - CDER: Virtual/remote human factor validation testing follow-up (internal reactive Q&A)
    - RADM Araojo presenting (via pre-recorded video) on Under-representation in Clinical Trials and the Implications for Drug Development, [HYPERLINK "https://www.aacr.org/meeting/aacr-annual-meeting-2020/aacr-virtual-annual-meeting-ii/"], including highlighting FDA OMHHE's ongoing efforts in response to COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Stakeholders/For%20clearance/20200622_AACRPanel%20.docx"] - talking points] 6/22
- Internal:
    - Updated Occupational Health employee QAs for InsideFDA in clearance (w/OO)
    - Working on new employee QAs on workplace reopening; in development
    - Updates to Occupational Health InsideFDA [HYPERLINK "http://inside.fda.gov:9003/EmployeeResources/EnvironmentSafetyandHealth/EmployeeSafetyOccupationalHealth/ucm017203.htm"], including updated clinic visit questionnaire [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-

OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Internal%20comms/20200611%20-%20JIC%20Clearance%20-%20COVID%2019%20OHS%20Questionnaire%20Revised.docx"]] and new social distancing flier for internal use

- InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Internal%20comms/20200529%20-%20Employee%20QA_Face%20Shield%20Alternative%20to%20Face%20Masks%20for%20Medical%20Concern.docx"]] - holding for reopening FDA plan

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, and other social media (e.g., Facebook, LinkedIn)
- Daily or as needed - updated PDFs listing EUAs for [HYPERLINK "https://www.fda.gov/media/136832/download"] and [HYPERLINK "https://www.fda.gov/media/136702/download"]
- 2x/ weekly ([HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/mcmi-newsletters"] & Fri): COVID-19 response recap emails to stakeholders
- Weekly (Wed) - [HYPERLINK "https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-04012020"]
- Weekly (Wed): Coronavirus Q&As for Consumers – top Q&A of week email to Consumer Update list
- Ongoing internal: additional [HYPERLINK "http://inside.fda.gov:9003/OC/OfficeofScientificMedicalPrograms/OfficeofCounter-TerrorismandEmergingThreats/COVID-19%20Information%20for%20FDA%20Staff/ucm646347.htm" \l "_blank"] for employees for InsideFDA, and responding to questions received from HHS employee portal

Published yesterday, June 16

- Press statements:
  - [HYPERLINK "https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-june-16-2020"] on topics including web FAQ updates on a new medical device adverse event reporting web page, a serology test EUA revocation, updated templates for developers that intend their assay to be used for pooling patient samples or for screening asymptomatic individuals, and a testing update
  - [HYPERLINK "https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chembio-antibody-test"]
  - [HYPERLINK "https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and"] (w/CDRH web updates)
- Emergency Use Authorizations:
  - Technical Safety Services LLC; [HYPERLINK "https://www.fda.gov/media/138954/download"] (~6/13)
  - Oceanetics, Inc.; [HYPERLINK "https://www.fda.gov/media/138955/download"] (~6/13)

  - Kaiser Permanente Mid-Atlantic States; [HYPERLINK "https://www.fda.gov/media/139066/download"] (molecular; home collection kit)
  - Applied BioCode Inc.; [HYPERLINK "https://www.fda.gov/media/139046/download"] (molecular)
  - Emory Medical Laboratories, Emory University Hospital; [HYPERLINK "https://www.fda.gov/media/139050/download"] (serological)
  - EUA revocation: Chembio Diagnostic System, Inc.; DPP COVID-19 IgM/IgG System - [HYPERLINK "https://www.fda.gov/media/139109/download"]
- Web updates:
  - CDRH: Asymptomatic Testing Updates to testing [HYPERLINK "https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2"], updated molecular diagnostic EUA [HYPERLINK "https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas"]
  - EUA archive page updates: [HYPERLINK "https://www.fda.gov/medical-devices/emergency-situations-medical-devices/historical-information-about-device-emergency-use-authorizations"], [HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization-archived-information" \l "covid19"]
- Stakeholders:
  - CDER: Drug Information Association (DIA) 2020 Virtual Global Annual Meeting: Regulatory Agility Under COVID 19 - Jeannie David (DSS)

SITREP ENDS

_____

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/default.aspx?RootFolder=%2Forgs%2FOC%2DOCET%2FOCETdocs%2FnCoV%2FShared%20Documents%2FJIC%20%2D%20FDA%20IMG%2FOps%20meeting%20coverage&FolderCTID=0x012000A3A7A055F609174BBA12CCD50BB2BD50&View=%7bAA5D576D-A152-4B9E-B345-979F92F9C4C9%7d"] updates (task forces, etc.)
- Hearings/Hill briefings
- NICCL calls (Tu/Th 10:15 a.m.)

MEDIA MONITORING

- See daily a.m. JIC email from Andrea Takash
- See [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/default.aspx?RootFolder=%2Forgs%2FOC%2DOCET%2FOCETdocs%2FnCoV%2FShared%20Documents%2FJIC%20%2D%20FDA%20IMG%2FNICCL%20JIC%20%28interagency%20comms%29&FolderCTID=0x012000A3A7A055F609174BBA12CCD50BB2BD50&View=%7bAA5D576D-A152-4B9E-B345-979F92F9C4C9%7d"] for social listening and other reports

###

From: Booze, Kristen [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=86338261BF6646C59BF8CF7C18D12DE3-KRISTEN.BOO]
Sent: 6/14/2020 3:51:57 PM
To: Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]
Subject: RE: CDER EUA actions QAs

Thanks! I'll review and let you know if I have any questions.

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Sunday, June 14, 2020 3:47 PM
To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Cc: Mair, Michael <Michael.Mair@fda.hhs.gov>; Hinton, Denise <Denise.Hinton@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>
Subject: RE: CDER EUA actions QAs

Attached are my comments and proposed edits.

CC:ing for others in OCET, in case they have any additional items to add, recognizing you have to move this along to the next person…

From: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Sent: Sunday, June 14, 2020 2:26 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: CDER EUA actions QAs
Importance: High

Hi Liz,

Thanks again for taking a look at these QAs. Attached are two sets of external QAs (they will be posted online):
1) For the HCQ/CQ revocation – These are the QAs we are most concerned with OCET reviewing. These will be posted on the EUA page to replace old QAs about the HCQ/CQ EUA. Some of this information is flagged for final checking against the memo, when it is final.
2) For the remdesivir revised FSs – feel free to look over, but OCET likely won't have edits. These will be added to already existing external QA document for remdesivir EUA.

Please let me know if you have any edits by 3:30, if possible.

Many thanks,
Kristen

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Sunday, June 14, 2020 12:34 PM
To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Subject: RE: CDER EUA actions QAs

k. thanks.

From: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Sent: Sunday, June 14, 2020 12:30 PM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: RE: CDER EUA actions QAs

Most likely will be closer to 2pm. Sorry. I'll send as soon as I have them back from CDER leadership.

From: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Sent: Saturday, June 13, 2020 10:38 PM
To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Subject: Re: CDER EUA actions QAs

I can review around 1:00. Thanks for the heads up.

From: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Date: June 13, 2020 at 8:39:36 PM EDT
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>
Subject: CDER EUA actions QAs

Hi Liz,

I'm working on external QAs for the HCQ/CQ EUA revocation. Andrew Leboeuf suggested that you review them before I send them to OCC for final review.

The QAs will likely be cleared around 1 or 2pm tomorrow (Sunday) and then I'll send them to you, if you will be available. We are working on a tight timeline to get them fully cleared by Monday morning. Will you be available to review around that time? If not, I can send them to you for a review after OCC clears them, which will likely be much later Sunday evening.

Thanks,
Kristen

Kristen Booze, MPH
Health Communications Specialist

Office of Communications, Division of Public Education and Outreach
Center for Drug Evaluation and Research
Office: (301) 796-7790 Mobile: (b) (6)
kristen.booze@fda.hhs.gov

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 6/10/2020 7:52:07 AM
To: 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: 10:00 JIC notes
Attachments: 20200610_JICMeetingNotes.docx

JIC daily check-in M-F, 10:00 – 10:30 a.m. **WebEx only**. For first part of meeting, we will run down status of current items, then focus on hot topics, if any. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

Reminders/notes/resources:

- **June 10, 2020:** COVID-19 and Communities of Color: Implications for Health Literacy NASEM webinar, 1:00 - 2:00 p.m.
- **June 10, 2020:** Resilience of the Research Enterprise During the COVID-19 Crisis: Science Communication During Crisis NASEM webinar, 2:00 - 4:00 p.m.
- CDC COVID-19 in Racial and Ethnic Minority Groups web page, including a recording of the recent webinar *COVID-19 Response: Promising Practices in Health Equity*

TODAY'S FOCUS DISCUSSION (Second half of meeting)

- Hot topics for the group

Pending, from previous discussions:

- 6/9 - need for evergreen messaging (tweets?) around need for continued preventive care (Azar OpEd - Stephanie C.)
- 6/5 - update on plans RE HCQ/CQ revocation, if any? (Anna S. looking into CDER division plans)
- 5/27 - future of FEMA How to Help web page (Brooke Courtney + web team)

Press/Media Engagements:

- What is Dr. Hahn up to today
- White House (TPs, when needed: Michael F.)

Then, by area:

- Press releases/media/WHTF
- CDRH
- CDER
- CBER
- CFSAN
- CVM
- ORA
- OPLIA
- CTP
- OCC
- OL
- Consumer
- Stakeholder
- Web
- Social

- Internal
- Meeting report-outs

SITREP

Published today, June 10

- Press statements:
  - Daily roundup [input here]
  - ...
- Emergency Use Authorizations: these 3 are posting now
  - Illumina, Inc.; Illumina COVIDSeq Test (molecular, first next-gen sequencing test)
  - ChromaCode Inc.; HDPCR SARS-CoV-2 Assay (molecular)
  - Warrior Diagnostics, Inc.; Warrior Diagnostics SARS-CoV-2 Assay (LDT)
- Web updates:
  - ...
- Stakeholders:
  - Pre-tape for BIO (virtual) conference fireside chat with Dr. Hahn aired today (+ additional FDA speakers presenting throughout the conference this week)
  - MCMi weekly email update (PDF) ++LINK
  - ...
- Consumers & patients:
  - ...
- Internal
  - ...

Likely today, June 10 [all internal confidential]

- Press statements:
  - FDA Authorizes First Next Generation Sequence Test for Diagnosing COVID-19 [SP link] - (Illumina)
- Emergency Use Authorizations:
  - Kaiser Permanente Mid-Atlantic home collection kit using Roche Cobas COVID-19 EUA assay – 6/9 **update?**
  - Fulgent/Picture Genetics; Nasal swab home collection kit – 6/9 **update?**
- Web updates:
  - CDRH: New Q&A: Hospital Beds, Stretchers, and Mattresses During the COVID-19 Public Health Emergency [SP link] - 6/10
  - CBER/ORA warning letter: Eucyt Laboratories, LLC, regarding products including an exosome product fraudulently marketed as a treatment or prevention of COVID-19 (+ roundup) - issued 6/5, posting 6/9 **update?**
- Stakeholders:
  - CDER/OTS Burst for Spotlight on CDER Science - Translating In Vitro Antiviral Activity to the In Vivo Setting: A Crucial Step in Fighting COVID-19 [SP link] – OCC cleared
- Consumers & patients:
  - FDA Voices: Rare Disease Therapy Development and Access Remain Top FDA Priorities During the Era of COVID-19 [SP link] - likely 6/10
- Internal
  - ...

Likely tomorrow, June 11 [all internal confidential]

- Press statements:
  - Daily roundup
  - ...
- Dr. Hahn media:

- ...
- Emergency Use Authorizations:
  - ...
- Web updates:
  - ...
- Stakeholders:
  - Pharmaceutical Care Management Association (PCMA) webinar (Drs. Shah and Guram) 6/11 (POC: Chaitali Patel) - recorded 6/9
  - ...
- Consumers & patients:
  - ...
- Internal
  - OCS: FDA IRB (Institutional Review Board) Interim Guidelines RE COVID-19 [SP link] ~6/11 (OCC has cleared)

Pending release, week of June 8 and beyond [all internal confidential]

- Press statements:
  - Daily roundups (M-F)
  - FDA Provides Update on Foreign, Domestic Routine Inspections Across Products, Announces New Approach to State Produce Inspections [SP link] and update on continuity of user fee related work for medical product reviews during pandemic [SP link] -- on hold pending senior leadership discussions / may be combined
  - CDRH statement on bundle of WLs to test kit manufacturers - later week of 6/8, or week of 6/15
- Dr. Hahn media:
  - Taping additional podcast footage 6/12 for new FDA podcast hosted by Dr. Shah (including COVID topics, but will also cover a variety of other FDA topics; podcast name TBD)
- CDRH:
  - Upcoming IIE guidances:
    - ...
  - EUAs:
    - ...
  - Web updates:
    - WLs - Operation Fraud Alert - fraudulent COVID products (CDRH, Jeremy Kahn)~mid June or later
  - Stakeholders:
    - CDRH: Webinar series on PPE – next 6/23
  - *Beyond this week:*
    - IIE guidances:
      - Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency ~week of 6/15 or later
      - Recalls of Medical Devices and Corrective Actions/Repairs of Electronic Products During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/15 or 6/22
      - Enforcement Policy for Coagulation Systems for Measurement of Viscoelastic Properties During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/15
      - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications – week of 6/22
      - Enforcement Policy for Non-invasive Electrical Stimulation Devices Intended for Treatment of Major Depressive Disorder (MDD) – week of 6/22
      - Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) – week of 7/5
      - Enforcement Policy for Digital Health and Stimulation Therapeutic Devices for Physical Rehabilitation – week of 7/5
    - EUAs:
      - Becton, Dickinson and Company, Veritor SARS-CoV-2 Assay

- Spectrum Solutions LLC, SDNA-1000 Saliva Collection Device
- Rapid Rona home collection kit using Hologic's Panther Fusion COVID-19 EUA assay – 6/18
- Additions to umbrella EUAs for various devices, ventilators, and support accessories

- CDER:
  - Revised EUA fact sheets for remdesivir, to update info on dosing and clinical trials, and add info on HCQ/CQ drug interaction with remdesivir (social, DR) ~6/12 or week of 6/15
  - *Beyond this week:*
    - Guidance: COVID-19 infection in Employees in Pharmaceutical Manufacturing (+Daily Roundup, listserv, reactive QAs) – late June
    - Guidance: Manufacturing, Supply Chain, and Drug Inspections During COVID-19 Public Health Emergency - Questions and Answers (+Daily Roundup) – late June
    - Guidance: Statistical Considerations for Clinical Trials During the COVID-19 Public Health Emergency - TBD
    - Health Affairs Blog: CDER's Contributions Towards Protecting Public Health During the COVID-19 Pandemic By Patrizia Cavazzoni, M.D. [SP link] - June/July
- CBER:
  - Use of stem cells (comms and target date TBD)
- CFSAN:
  - Checklist (w/CVM): Employee Health and Food Safety Checklist for Human and Animal Food Operations During COVID-19 [SP link]
- CVM:
  - *(see consumer below for pet video update)*
- ORA:
  - Guidance: Disinfection of Surfaces on Interstate Conveyances (OMA clearance)
- OPLIA:
  - Potentially a new blog by Europe office, emphasizing EU collaboration (platform/details TBD)
  - Feature on ORA employee's experience being in India during pandemic and visiting hydroxychloroquine plant [internal to ORA + external comms TBD]
- CTP:
  - ...
- Consumer & patient updates:
  - Language translation of FAQs on face coverings and for DIY ventilator makers
  - Getting Smarter About Food Safety: The Pandemic and Lessons Learned (based on similar FDA Voices)
  - Video on COVID-19 and pets (companion to previously published Consumer Update) - week of 6/8
- Web updates:
  - OC/CDRH: User-friendly tool on website for labs that need information on test component substitutes when supply issues arise (+ webinar)
  - OCET: New page: Updates on activities performed under the rapid response to COVID-19 3D printing MOU (w/NIH, VA) [SP link] ~maybe week of 6/8
- Stakeholders:
  - C-PATH press release: C-Path Launches CURE Drug Repurposing Collaboratory to Accelerate Identification of Existing Drugs to Treat Infectious Diseases, Including COVID-19 (FDA-funded work, including an FDA quote) - week of 6/8? [SP link]
  - CDER: Virtual/remote human factor validation testing follow-up (internal reactive Q&A)
  - OEA: Stakeholder toolkit for Convalescent Plasma, including fact sheet, tweets, and newsletter content (some materials in toolkit now available in Spanish) - likely week of 6/8
  - Drug Information Association (DIA) 2020 Virtual Global Annual Meeting: Regulatory Agility Under COVID 19 -Jeannie David (DSS) – 6/16
  - SES: Dr. Hahn to provide opening remarks on call with American Hospital Association (membership meeting about 700 members) - planning phase - 6/18
  - MedDRA User's Group webinar: Impact of COVID-19 on pharmacovigilance, Sonja Brajovic (OSE) – 6/18

- RADM Araojo presenting (via pre-recorded video) on Under-representation in Clinical Trials and the Implications for Drug Development, AACR Virtual Annual Meeting II, including highlighting FDA OMHHE's ongoing efforts in response to COVID-19 [SP link - talking points] 6/22

- Internal:
  - Updated Occupational Health employee QAs for InsideFDA in clearance
  - Working on new employee QAs on workplace reopening; in development
  - InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [SP link] - holding for reopening FDA plan

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, and other social media (e.g., Facebook, LinkedIn)
- Daily or as needed - updated PDFs listing EUAs for therapeutics and medical devices
- 2x/ weekly (Wed & Fri): COVID-19 response recap emails to stakeholders
- Weekly (Wed) - Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
- Weekly (Wed): Coronavirus Q&As for Consumers – top Q&A of week email to Consumer Update list
- Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA, and responding to questions received from HHS employee portal

Published yesterday, June 9

- Press statements:
  - Daily roundup on topics including a new ANDA, a CDER warning letter, and a testing update
- Dr. Hahn media:
  - 7:50-8:00 a.m. Bo Thompson morning show, Charlotte, NC
  - 8:05-8:15 a.m. Drew Steele show, Fort Myers, FL
- Emergency Use Authorizations:
  - Euroimmun; EURORealTime SARS-CoV-2 (molecular)
  - Siemens Healthcare Diagnostics Inc.; Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (serology)
  - Siemens Healthcare Diagnostics Inc.; Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (serology)
- Web updates:
  - CDER WL: organic-beauty-recipes.com selling essential oils (issued 6/8)
  - CDER: ANDA Approval: Succinylcholine Chloride Injection USP, 200 mg/10 mL (20 mg/mL), Multiple-Dose Vial (ANDA 213431), which facilitates tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation (approved 6/8, posted 6/9)
  - CDER/OTS: Burst for Spotlight on CDER Science: Translating In Vitro Antiviral Activity to the In Vivo Setting: A Crucial Step in Fighting COVID-19
  - CDER: Update to Compounding Activities | COVID-19 page on product reporting from outsourcing facilities
  - ORA: update on FDA face covering policy and signage at FDA spaces: FDA Import Offices and Ports of Entry
  - COVID-19 Page FAQ updates to help public better understand FDA's role. Updated answers:
    - Q: What is the FDA doing to respond to the COVID-19 pandemic?
    - Q: What is an emergency use authorization and how is it being used to respond to COVID-19?
    - Q: How does COVID-19 spread?
    - Q: What is the FDA's role in approving vaccines and what is being done to produce a COVID-19 vaccine?
    - Q: What does it mean to be an FDA-approved drug?
    - Q: What is the FDA's role in regulating potential treatments during a public health emergency?
    - Q: What is the FDA's role in helping to ensure the safety of the human and animal food supply?

- Q: What is the FDA's role in regulating animal drugs, animal food (including pet food), and animal medical devices?

- Stakeholders:
  - CDRH: Webinar Series - Respirators for Health Care Personnel Use during COVID-19 Pandemic - first event in series + email including save-the-date for next webinar on 6/23
  - CDER: Hand sanitizer internal reactive QA [SP link]
  - CDER: Division of Drug Information CURE ID webinar for HCPs - Capturing Clinician's Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-1 – Speaker Heather Stone (OMP) + web page update (outreach/SM pending)
  - CFSAN/OFPR - FDA call with produce industry to discuss CDC guidance on farm workers and employers and recent FDA guidances relevant to that industry. CDC and OSHA also participated in the call.

SITREP ENDS

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- NICCL calls (Tu/Th 10:15 a.m.)

MEDIA MONITORING

- See daily a.m. JIC email from Andrea Takash
- See NICCL JIC folder for social listening and other reports

###

April Finnen
IMG JIC Section Chief
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)
U.S. Food and Drug Administration
Cell: 240-507-7742 ←Call this # or IM/Skype to reach me
Email: april.finnen@fda.hhs.gov
JIC (Joint Information Center) leads email: 2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov

Agenda and notes – JIC 10:00 a.m. check-in

June 9, 2020

JIC daily check-in M-F, 10:00 – 10:30 a.m. **WebEx only**. For first part of meeting, we will run down status of current items, then focus on hot topics, if any. After the meeting, updated notes will be available in SharePoint (JIC [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/default.aspx?RootFolder=%2Forgs%2FOC%2DOCET%2FOCETdocs%2FnCoV%2FShared%20Documents%2FJIC%20%2D%20FDA%20IMG%2FMeeting%20notes&FolderCTID=0x012000A3A7A055F609174BBA12CCD50BB2BD50&View=%7bAA5D576D-A152-4B9E-B345-979F92F9C4C9%7d"]).

Reminders/notes/resources:

- **June 10, 2020:** [HYPERLINK "https://www.eventbrite.com/e/covid-19-and-communities-of-color-implications-for-health-literacy-tickets-107601745718"] NASEM webinar, 1:00 - 2:00 p.m.
- Just FYI - [HYPERLINK "https://www.nytimes.com/interactive/2020/06/08/upshot/when-epidemiologists-will-do-everyday-things-coronavirus.html"] (NY Times)

TODAY'S FOCUS DISCUSSION (Second half of meeting)

- Hot topics for the group

Pending, from previous discussions:

- 6/5 - update on plans RE HCQ/CQ revocation, if any? (Anna S. looking into CDER division plans)
- 5/27 - future of FEMA How to Help web page (Brooke Courtney + web team)

Press/Media Engagements:

- What is Dr. Hahn up to today
- White House (TPs, when needed: Michael F.)

Then, by area:

- Press releases/media/WHTF
- CDRH
- CDER
- CBER
- CFSAN
- CVM
- ORA
- OPLIA
- CTP
- OCC
- OL
- Consumer
- Stakeholder
- Web
- Social
- Internal
- Meeting report-outs

SITREP

Published today, June 9

- Press statements:
  - Daily roundup on topics including … [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/2020.06.09.docx"]]
  - …
- Dr. Hahn media:
  - 7:50-8:00 a.m. Bo Thompson morning show, Charlotte, NC
  - 8:05-8:15 a.m. Drew Steele show, Fort Myers, FL
- Emergency Use Authorizations:
  - …
- Web updates:
  - …
- Stakeholders:
  - CDRH: [HYPERLINK "https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/webinar-series-respirators-health-care-personnel-use-during-covid-19-pandemic-06092020-06092020"] - first event in series [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDRH/20200609-Respirator_Webinar2.0.pptx"] - SP link]
  - CDER: [HYPERLINK "https://www.fda.gov/about-fda/fda-pharmacy-student-experiential-program/fda-drug-topics-cure-id-capturing-clinicians-experiences-repurposing-drugs-inform-future-studies-era"] for HCPs - Capturing Clinician's Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-1 – Speaker Heather Stone (OMP) + outreach/SM/ webpage – 6/9
  - CFSAN: Support CDC guidance on farm workers and employers + stakeholder call ~6/9
- Consumers & patients:
  - FDA Voices: Rare Disease Therapy Development and Access Remain Top FDA Priorities During the Era of COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Consumer/20200604%20FDA%20Voices%20ALS%20Rare%20disease%20JIC.docx"]] - likely 6/9 or 6/10
- Internal
  - InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Internal%20comms/20200529%20-%20Employee%20QA_Face%20Shield%20Alternative%20to%20Face%20Masks%20for%20Medical%20Concern.docx"]]

Likely today, June 9 [all internal confidential]

- Press statements:
  - Daily roundup on topics including … [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/2020.06.09.docx"]]

  - FDA Authorizes First Next Generation Sequence Test for Diagnosing COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/Illumina%20NGS%20testV2.docx"]] - likely 6/9
- Dr. Hahn media:
  - 7:50-8:00 a.m. Bo Thompson morning show, Charlotte, NC
  - 8:05-8:15 a.m. Drew Steele show, Fort Myers, FL
- Emergency Use Authorizations:
  - Euroimmun; EURORealTime SARS-CoV-2 (molecular) auth. 6/8
  - Siemens Healthcare Diagnostics Inc.; Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (serology) auth. 6/8
  - Siemens Healthcare Diagnostics Inc.; Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (serology) auth. 6/8
  - ...
- Web updates:
  - CDER WL: Organic Beauty Products (issuing 6/8)
  - CDER: disinfectant tunnels update to main FDA FAQs 6/9?
  - CBER/ORA warning letter: Eucyt Laboratories, LLC, regarding products manufactured by the firm including an exosome product fraudulently marketed as a treatment or prevention of COVID-19 (+ roundup) issued 6/5, posting TBD **(ORA checking status)**
- Stakeholders:
  - CDRH: Webinar Series: SAVE THE DATE for next webinar on 6/23 shared via CDRH email subscription
  - CFSAN: Support CDC guidance on farm workers and employers + stakeholder call ~6/9
- Consumers & patients:
  - FDA Voices: Rare Disease Therapy Development and Access Remain Top FDA Priorities During the Era of COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Consumer/20200604%20FDA%20Voices%20ALS%20Rare%20disease%20JIC.docx"]] - likely 6/9 or 6/10
- Internal
  - InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Internal%20comms/20200529%20-%20Employee%20QA_Face%20Shield%20Alternative%20to%20Face%20Masks%20for%20Medical%20Concern.docx"]]

Likely tomorrow, June 10 [all internal confidential]

- Press statements:
  - Daily roundup
  - ...
- Dr. Hahn media:
  - ...
- Emergency Use Authorizations:
  - ...
- Web updates:
  - ...
- Stakeholders:

  - Pre-tape for BIO (virtual) conference [HYPERLINK "https://www.bio.org/events/bio-digital/sessions/677784"] with Dr. Hahn will air 6/10
  - MCMi weekly email update [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Stakeholders/For%20clearance/20200610_MCMiemail.docx"]]
  - ...
- Consumers & patients:
  - ...
- Internal
  - ...

***Pending release, week of June 8 and beyond** [all internal confidential]*

- Press statements:
  - Daily roundups (M-F)
  - FDA provides update on continuity of user fee related work for medical product reviews during pandemic [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/draft%20user%20fee%20update%205.27.20.docx"]] - later week of 6/8
  - FDA Provides Update on Foreign, Domestic Routine Inspections Across Products, Announces New Approach to State Produce Inspections potentially ~6/9 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/FDA%20Inspections_6.6.20.docx"]]
- Dr. Hahn media:
  - Taping additional podcast footage 6/12 for new FDA podcast hosted by Dr. Shah (including COVID topics, but will also cover a variety of other FDA topics; podcast name TBD)
- CDRH:
  - Upcoming IIE guidances:
    - Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency ~week of 6/15
    - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications – week of 6/8 or 6/15
    - Enforcement Policy for Non-invasive Electrical Stimulation Devices Intended for Treatment of Major Depressive Disorder (MDD) – week of 6/8 or 6/15
  - EUAs:
    - ...
  - Web updates:
    - WLs - Operation Fraud Alert - fraudulent COVID products (CDRH, Jeremy Kahn)~mid June or later
    - New Q&A: Hospital Beds, Stretchers, and Mattresses During the COVID-19 Public Health Emergency [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDRH/FAQS%20HOSPITAL%20BEDS%20AND%20STRETCHERS%20OPEQ%20CLEARED.docx"]] week of 6/8?
  - Stakeholders:
    - CDRH: Webinar series on PPE – 6/23
  - *Beyond this week:*

    - IIE guidances:
        - Enforcement Policy for Digital Health and Stimulation Therapeutic Devices for Physical Rehabilitation – week of 6/15
        - Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) – week of 6/15
        - Recalls of Medical Devices and Corrective Actions/Repairs of Electronic Products During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/15
        - Enforcement Policy for Coagulation Systems for Measurement of Viscoelastic Properties During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/15
    - EUAs:
        - Gravity Dx's molecular LDT to the umbrella EUA
        - Becton, Dickinson and Company, Veritor SARS-CoV-2 Assay
        - Spectrum Solutions LLC, SDNA-1000 Saliva Collection Device
        - Rapid Rona home collection kit using Hologic's Panther Fusion COVID-19 EUA assay
        - Kaiser Permanente Mid-Atlantic home collection kit using Roche Cobas COVID-19 EUA assay
        - Additions to umbrella EUAs for various devices, ventilators, and support accessories
- CDER:
    - Warning letter: Organic-beauty-recipes.com selling essential oils (from CDER ops sitrep - no date)
    - Updated Remdesivir HealthCare Professional Fact Sheets – 6/12 or next week
    - Revised EUA fact sheets for remdesivir, to update info on dosing and clinical trials, and add info on HCQ/CQ drug interaction with remdesivir ~6/12 or week of 6/15
    - *Beyond this week:*
        - Guidance: COVID-19 infection in Employees in Pharmaceutical Manufacturing (+Daily Roundup, listserv, reactive QAs) – late June
        - Guidance: Manufacturing, Supply Chain, and Drug Inspections During COVID-19 Public Health Emergency - Questions and Answers (+Daily Roundup) – late June
        - Health Affairs Blog: CDER's Contributions Towards Protecting Public Health During the COVID-19 Pandemic By Patrizia Cavazzoni, M.D. [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDER/HACDERWorkCovid19PandemicJune4.docx"]] - June/July
- CBER:
    - Use of stem cells (comms and target date TBD)
- CFSAN:
    - Checklist (w/CVM): Employee Health and Food Safety Checklist for Human and Animal Food Operations During COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OFVM/OFVM%20landing%20page/Cross_Cutting_Issues/Shared%20Documents/FSMA%202019-2020/FSMA%20and%20COVID-19/Employee%20Health%20Food%20Safety%20-Checklist-for-reopening-and-operation-changes%20515TS.docx"]]
- CVM:

  - ...
- ORA:
  - Guidance: Disinfection of Surfaces on Interstate Conveyances (OMA clearance)
- OPLIA:
  - Feature to go in ORAcle on ORA employee's experience being in India during pandemic and visiting hydroxychloroquine plant [internal to ORA + external comms TBD]
- CTP:
  - ...
- Consumer & patient updates:
  - Language translation of FAQs on face coverings and for DIY ventilator makers
  - Getting Smarter About Food Safety: The Pandemic and Lessons Learned (based on similar FDA Voices)
- Web updates:
  - OC/CDRH: User-friendly tool on website for labs that need information on test component substitutes when supply issues arise (+ webinar)
  - OCET: New page: Updates on activities performed under the rapid response to COVID-19 3D printing [HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/fda-efforts-connect-manufacturers-and-health-care-entities-fda-department-veterans-affairs-national"] (w/NIH, VA) [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDRH/20200522_3DprintMOU_update.docx"]] ~maybe week of 6/8
- Stakeholders:
  - Pharmaceutical Care Management Association (PCMA) [HYPERLINK "https://www.pcmanet.org/pcma-event/pcma-spring-webinar-series-2020/"] (Drs. Shah and Guram) 6/11 - TPs forthcoming for JIC/OCC clearance (POC: Chaitali Patel)
  - C-PATH press release: C-Path Launches CURE Drug Repurposing Collaboratory to Accelerate Identification of Existing Drugs to Treat Infectious Diseases, Including COVID-19 (FDA-funded work, including an FDA quote) - week of 6/8? [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Press/For%20clearance/CURE_PPP-Draft_PressRelease-6%208%2020.docx"]]
  - CDER: Virtual/remote human factor validation testing follow-up (internal reactive Q&A)
  - OEA: Stakeholder toolkit for Convalescent Plasma, including fact sheet, tweets, and newsletter content (some materials in toolkit now available in Spanish) - likely week of 6/8
  - Drug Information Association (DIA) 2020 Virtual Global Annual Meeting: Regulatory Agility Under COVID 19 -Jeannie David (DSS) – 6/16
  - SES: Dr. Hahn to provide opening remarks on call with American Hospital Association (membership meeting about 700 members) - planning phase - 6/18
  - MedDRA User's Group webinar: Impact of COVID-19 on pharmacovigilance, Sonja Brajovic (OSE) – 6/18
  - RADM Araojo presenting (via pre-recorded video) on Under-representation in Clinical Trials and the Implications for Drug Development, [HYPERLINK "https://www.aacr.org/meeting/aacr-annual-meeting-2020/aacr-virtual-annual-meeting-ii/"], including highlighting FDA OMHHE's ongoing efforts in response to COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Stakeholders/For%20clearance/20200622_AACRPanel%20.docx"] - talking points] 6/22
- Internal:

- Updated Occupational Health employee QAs for InsideFDA in clearance
- Working on new employee QAs on workplace reopening; in development
- OCS: FDA IRB (Institutional Review Board) Interim Guidelines RE COVID-19 [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/Other%20-%20for%20clearance/20200605_OCS_IRB_interim_guidelines.docx"]] ~6/11

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, and other social media (e.g., Facebook, LinkedIn)
- Daily or as needed - updated PDFs listing EUAs for [HYPERLINK "https://www.fda.gov/media/136832/download"] and [HYPERLINK "https://www.fda.gov/media/136702/download"]
- 2x/ weekly ([HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/about-mcmi/mcmi-newsletters"] & Fri): COVID-19 response recap emails to stakeholders
- Weekly (Wed) - [HYPERLINK "https://www.fda.gov/medical-devices/workshops-conferences-medical-devices/virtual-town-hall-series-immediately-effect-guidance-coronavirus-covid-19-diagnostic-tests-04012020"]
- Weekly (Wed): Coronavirus Q&As for Consumers – top Q&A of week email to Consumer Update list
- Ongoing internal: additional [HYPERLINK "http://inside.fda.gov:9003/OC/OfficeofScientificMedicalPrograms/OfficeofCounter-TerrorismandEmergingThreats/COVID-19%20Information%20for%20FDA%20Staff/ucm646347.htm" \l "_blank"] for employees for InsideFDA, and responding to questions received from HHS employee portal

Published yesterday, June 8

- Press statements:
  - [HYPERLINK "https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-june-8-2020"] on topics including revisions to some respirator EUAs, a new guidance, a new ventilator EUA, two new web pages, and a testing update
- Dr. Hahn media:
  - HHS Learning Curve podcast: [HYPERLINK "https://podcasts.apple.com/us/podcast/ep4-the-fda-science-in-action/id1514670547?i=1000476974288"] interview w/Dr. Hahn (6/5)
- Emergency Use Authorizations:
  - Genetron Health (Beijing) Co., Ltd.; [HYPERLINK "https://www.fda.gov/media/138682/download"] (molecular)
  - BioMedInnovations SuppleVent Ventilator added to [HYPERLINK "https://www.fda.gov/media/136528/download"](note: don't see it added yet, but 6/8 DR says added to 3/24 vent EUA)
- Web updates:
  - New web page: [HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/innovation-respond-covid-19"] - Includes links to and descriptions of the new partnerships FDA is leading or participating in to respond to COVID-19

  - New web page: [HYPERLINK "https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-educational-resources"] - Includes links to all the videos, fact sheets and social media toolkits that FDA has created on COVID-19
  - CDER: Sanitizing Tunnels QA - one [HYPERLINK "https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19"]and one internal QA [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDER/REACTIVE%20QAs_disinfectant%20tunnels_CDER%20cleared.docx"]]
- Stakeholders:
  - CDER Guidance: [HYPERLINK "https://www.fda.gov/regulatory-information/search-fda-guidance-documents/temporary-policy-prescription-drug-marketing-act-requirements-distribution-drug-samples-during-covid"]
  - FDA [HYPERLINK "https://twitter.com/US_FDA/status/1265251336842473472"] the Muscular Dystrophy Association for the MDA Advocacy Institute: A COVID-19 [HYPERLINK "https://forms.office.com/Pages/ResponsePage.aspx?id=GIjAaRdcmkSXkLYKPH5SIrtTApbGw-ZJhk_lx4uzAbRUNjY1Wjg5NDBMMkU2MjhWWDBIMDRXUDlVUS4u"] with the FDA
  - CDER: Revised coursework: [HYPERLINK "https://www.accessdata.fda.gov/cder/dr/course/framework/index.html"]-OCC cleared, not posting until 2021
  - CDER: Hand Sanitizer--new content for [HYPERLINK "https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19"] on disinfectant tunnels; update to main FDA FAQs; internal reactive QA [[HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/JIC%20-%20FDA%20IMG/CDER/Hand%20Sanitizer%20COVID%2019%20Guidances%20QA_UPDATES_06.01.20.docx"]] **CDER - please confirm this is done - left the main FAQ update under likely today**
  - SES: Stakeholder call – Arthritis Foundation
  - SES: Stakeholder call – American College of Rheumatology
  - Oncology listening session on COVID

SITREP ENDS

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/default.aspx?RootFolder=%2Forgs%2FOC%2DOCET%2FOCETdocs%2FnCoV%2FShared%20Documents%2FJIC%20%2D%20FDA%20IMG%2FOps%20meeting%20coverage&FolderCTID=0x012000A3A7A055F609174BBA12CCD50BB2BD50&View=%7bAA5D576D-A152-4B9E-B345-979F92F9C4C9%7d"] updates (task forces, etc.)
- Hearings/Hill briefings
- NICCL calls (Tu/Th 10:15 a.m.)

MEDIA MONITORING

- See daily a.m. JIC email from Andrea Takash

- See [HYPERLINK "http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/default.aspx?RootFolder=%2Forgs%2FOC%2DOCET%2FOCETdocs%2FnCoV%2FShared%20Documents%2FJIC%20%2D%20FDA%20IMG%2FNICCL%20JIC%20%28interagency%20comms%29&FolderCTID=0x012000A3A7A055F609174BBA12CCD50BB2BD50&View=%7bAA5D576D-A152-4B9E-B345-979F92F9C4C9%7d"] for social listening and other reports

###

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 6/9/2020 7:49:25 AM
To: 2019-nCoV FDA IMG JIC [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=289715a1146847558b07a33ccab6bccf-2019-nCoV F]
CC: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Hinton, Denise [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=85feca0be0694803be6030e97c7b4adb-HINTOND]
Subject: 10:00 JIC notes
Attachments: 20200609_JICMeetingNotes.docx

JIC daily check-in M-F, 10:00 – 10:30 a.m. **WebEx only**. For first part of meeting, we will run down status of current items, then focus on hot topics, if any. After the meeting, updated notes will be available in SharePoint (JIC meeting notes folder).

Reminders/notes/resources:

- **June 10, 2020:** COVID-19 and Communities of Color: Implications for Health Literacy NASEM webinar, 1:00 - 2:00 p.m.
- Just FYI - When 511 Epidemiologists Expect to Fly, Hug and Do 18 Other Everyday Activities Again (NY Times)

TODAY'S FOCUS DISCUSSION (Second half of meeting)

- Hot topics for the group

Pending, from previous discussions:

- 6/5 - update on plans RE HCQ/CQ revocation, if any? (Anna S. looking into CDER division plans)
- 5/27 - future of FEMA How to Help web page (Brooke Courtney + web team)

Press/Media Engagements:

- What is Dr. Hahn up to today
- White House (TPs, when needed: Michael F.)

Then, by area:

- Press releases/media/WHTF
- CDRH
- CDER
- CBER
- CFSAN
- CVM
- ORA
- OPLIA
- CTP
- OCC
- OL
- Consumer
- Stakeholder
- Web
- Social
- Internal
- Meeting report-outs

SITREP

Published today, June 9

- Press statements:
  - Daily roundup on topics including … [input here]
  - …
- Dr. Hahn media:
  - 7:50-8:00 a.m. Bo Thompson morning show, Charlotte, NC
  - 8:05-8:15 a.m. Drew Steele show, Fort Myers, FL
- Emergency Use Authorizations:
  - …
- Web updates:
  - …
- Stakeholders:
  - CDRH: Webinar Series - Respirators for Health Care Personnel Use during COVID-19 Pandemic - first event in series [slides - SP link]
  - CDER: Division of Drug Information CURE ID webinar for HCPs - Capturing Clinician's Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-1 – Speaker Heather Stone (OMP) + outreach/SM/ webpage – 6/9
  - CFSAN: Support CDC guidance on farm workers and employers + stakeholder call ~6/9
- Consumers & patients:
  - FDA Voices: Rare Disease Therapy Development and Access Remain Top FDA Priorities During the Era of COVID-19 [SP link] - likely 6/9 or 6/10
- Internal
  - InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [SP link]

Likely today, June 9 [all internal confidential]

- Press statements:
  - Daily roundup on topics including … [input here]
  - FDA Authorizes First Next Generation Sequence Test for Diagnosing COVID-19 [SP link] - likely 6/9
- Dr. Hahn media:
  - 7:50-8:00 a.m. Bo Thompson morning show, Charlotte, NC
  - 8:05-8:15 a.m. Drew Steele show, Fort Myers, FL
- Emergency Use Authorizations:
  - Euroimmun; EURORealTime SARS-CoV-2 (molecular) auth. 6/8
  - Siemens Healthcare Diagnostics Inc.; Dimension Vista SARS-CoV-2 Total antibody assay (COV2T) (serology) auth. 6/8
  - Siemens Healthcare Diagnostics Inc.; Dimension EXL SARS-CoV-2 Total antibody assay (CV2T) (serology) auth. 6/8
  - …
- Web updates:
  - CDER WL: Organic Beauty Products (issuing 6/8)
  - CDER: disinfectant tunnels update to main FDA FAQs 6/9?
  - CBER/ORA warning letter: Eucyt Laboratories, LLC, regarding products manufactured by the firm including an exosome product fraudulently marketed as a treatment or prevention of COVID-19 (+ roundup) issued 6/5, posting TBD **(ORA checking status)**
- Stakeholders:
  - CDRH: Webinar Series: SAVE THE DATE for next webinar on 6/23 shared via CDRH email subscription
  - CFSAN: Support CDC guidance on farm workers and employers + stakeholder call ~6/9
- Consumers & patients:
  - FDA Voices: Rare Disease Therapy Development and Access Remain Top FDA Priorities During the Era of COVID-19 [SP link] - likely 6/9 or 6/10

- Internal
  - InsideFDA: Face Shield Alternative to Face Mask for Medical Concerns [SP link]

***Likely tomorrow, June 10** [all internal confidential]*

- Press statements:
  - Daily roundup
  - ...
- Dr. Hahn media:
  - ...
- Emergency Use Authorizations:
  - ...
- Web updates:
  - ...
- Stakeholders:
  - Pre-tape for BIO (virtual) conference fireside chat with Dr. Hahn will air 6/10
  - MCMi weekly email update [SP link]
  - ...
- Consumers & patients:
  - ...
- Internal
  - ...

***Pending release, week of June 8 and beyond** [all internal confidential]*

- Press statements:
  - Daily roundups (M-F)
  - FDA provides update on continuity of user fee related work for medical product reviews during pandemic [SP link] - later week of 6/8
  - FDA Provides Update on Foreign, Domestic Routine Inspections Across Products, Announces New Approach to State Produce Inspections potentially ~6/9 [SP link]
- Dr. Hahn media:
  - Taping additional podcast footage 6/12 for new FDA podcast hosted by Dr. Shah (including COVID topics, but will also cover a variety of other FDA topics; podcast name TBD)
- CDRH:
  - Upcoming IIE guidances:
    - Enforcement Policy for Viral Transport Media During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency ~week of 6/15
    - Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications – week of 6/8 or 6/15
    - Enforcement Policy for Non-invasive Electrical Stimulation Devices Intended for Treatment of Major Depressive Disorder (MDD) – week of 6/8 or 6/15
  - EUAs:
    - ...
  - Web updates:
    - WLs - Operation Fraud Alert - fraudulent COVID products (CDRH, Jeremy Kahn)~mid June or later
    - New Q&A: Hospital Beds, Stretchers, and Mattresses During the COVID-19 Public Health Emergency [SP link] week of 6/8?
  - Stakeholders:
    - CDRH: Webinar series on PPE – 6/23
  - *Beyond this week:*
    - IIE guidances:

- Enforcement Policy for Digital Health and Stimulation Therapeutic Devices for Physical Rehabilitation – week of 6/15
- Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (Revised) – week of 6/15
- Recalls of Medical Devices and Corrective Actions/Repairs of Electronic Products During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/15
- Enforcement Policy for Coagulation Systems for Measurement of Viscoelastic Properties During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency – week of 6/15
- EUAs:
- Gravity Dx's molecular LDT to the umbrella EUA
- Becton, Dickinson and Company, Veritor SARS-CoV-2 Assay
- Spectrum Solutions LLC, SDNA-1000 Saliva Collection Device
- Rapid Rona home collection kit using Hologic's Panther Fusion COVID-19 EUA assay
- Kaiser Permanente Mid-Atlantic home collection kit using Roche Cobas COVID-19 EUA assay
- Additions to umbrella EUAs for various devices, ventilators, and support accessories

- CDER:
  - Warning letter: Organic-beauty-recipes.com selling essential oils (from CDER ops sitrep - no date)
  - Updated Remdesivir HealthCare Professional Fact Sheets – 6/12 or next week
  - Revised EUA fact sheets for remdesivir, to update info on dosing and clinical trials, and add info on HCQ/CQ drug interaction with remdesivir ~6/12 or week of 6/15
  - *Beyond this week:*
    - Guidance: COVID-19 infection in Employees in Pharmaceutical Manufacturing (+Daily Roundup, listserv, reactive QAs) – late June
    - Guidance: Manufacturing, Supply Chain, and Drug Inspections During COVID-19 Public Health Emergency - Questions and Answers (+Daily Roundup) – late June
    - Health Affairs Blog: CDER's Contributions Towards Protecting Public Health During the COVID-19 Pandemic By Patrizia Cavazzoni, M.D. [SP link] - June/July
- CBER:
  - Use of stem cells (comms and target date TBD)
- CFSAN:
  - Checklist (w/CVM): Employee Health and Food Safety Checklist for Human and Animal Food Operations During COVID-19 [SP link]
- CVM:
  - …
- ORA:
  - Guidance: Disinfection of Surfaces on Interstate Conveyances (OMA clearance)
- OPLIA:
  - Feature to go in ORAcle on ORA employee's experience being in India during pandemic and visiting hydroxychloroquine plant [internal to ORA + external comms TBD]
- CTP:
  - …
- Consumer & patient updates:
  - Language translation of FAQs on face coverings and for DIY ventilator makers
  - Getting Smarter About Food Safety: The Pandemic and Lessons Learned (based on similar FDA Voices)
- Web updates:
  - OC/CDRH: User-friendly tool on website for labs that need information on test component substitutes when supply issues arise (+ webinar)
  - OCET: New page: Updates on activities performed under the rapid response to COVID-19 3D printing MOU (w/NIH, VA) [SP link] ~maybe week of 6/8
- Stakeholders:
  - Pharmaceutical Care Management Association (PCMA) webinar (Drs. Shah and Guram) 6/11 - TPs forthcoming for JIC/OCC clearance (POC: Chaitali Patel)

- C-PATH press release: C-Path Launches CURE Drug Repurposing Collaboratory to Accelerate Identification of Existing Drugs to Treat Infectious Diseases, Including COVID-19 (FDA-funded work, including an FDA quote) - week of 6/8? [SP link]
- CDER: Virtual/remote human factor validation testing follow-up (internal reactive Q&A)
- OEA: Stakeholder toolkit for Convalescent Plasma, including fact sheet, tweets, and newsletter content (some materials in toolkit now available in Spanish) - likely week of 6/8
- Drug Information Association (DIA) 2020 Virtual Global Annual Meeting: Regulatory Agility Under COVID 19 -Jeannie David (DSS) – 6/16
- SES: Dr. Hahn to provide opening remarks on call with American Hospital Association (membership meeting about 700 members) - planning phase - 6/18
- MedDRA User's Group webinar: Impact of COVID-19 on pharmacovigilance, Sonja Brajovic (OSE) – 6/18
- RADM Araojo presenting (via pre-recorded video) on Under-representation in Clinical Trials and the Implications for Drug Development, AACR Virtual Annual Meeting II, including highlighting FDA OMHHE's ongoing efforts in response to COVID-19 [SP link - talking points] 6/22

- Internal:
  - Updated Occupational Health employee QAs for InsideFDA in clearance
  - Working on new employee QAs on workplace reopening; in development
  - OCS: FDA IRB (Institutional Review Board) Interim Guidelines RE COVID-19 [SP link] ~6/11

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, and other social media (e.g., Facebook, LinkedIn)
- Daily or as needed - updated PDFs listing EUAs for therapeutics and medical devices
- 2x/ weekly (Wed & Fri): COVID-19 response recap emails to stakeholders
- Weekly (Wed) - Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
- Weekly (Wed): Coronavirus Q&As for Consumers – top Q&A of week email to Consumer Update list
- Ongoing internal: additional InsideFDA FAQs for employees for employees for InsideFDA, and responding to questions received from HHS employee portal

Published yesterday, June 8

- Press statements:
  - Daily roundup on topics including revisions to some respirator EUAs, a new guidance, a new ventilator EUA, two new web pages, and a testing update
- Dr. Hahn media:
  - HHS Learning Curve podcast: The FDA: Science in Action interview w/Dr. Hahn (6/5)
- Emergency Use Authorizations:
  - Genetron Health (Beijing) Co., Ltd.; Genetron SARS-CoV-2 RNA Test (molecular)
  - BioMedInnovations SuppleVent Ventilator added to Appendix B (note: don't see it added yet, but 6/8 DR says added to 3/24 vent EUA)
- Web updates:
  - New web page: Innovation to Respond to COVID-19 - Includes links to and descriptions of the new partnerships FDA is leading or participating in to respond to COVID-19
  - New web page: COVID-19 Educational Resources - Includes links to all the videos, fact sheets and social media toolkits that FDA has created on COVID-19
  - CDER: Sanitizing Tunnels QA - one external and one internal QA [SP link]
- Stakeholders:
  - CDER Guidance: Temporary Policy on Prescription Drug Marketing Act Requirements for Distribution of Drug Samples During the COVID-19 Public Health Emergency
  - FDA joined the Muscular Dystrophy Association for the MDA Advocacy Institute: A COVID-19 Discussion with the FDA

- CDER: Revised coursework: FDA's Role in Public Health: Drug Efficacy, Safety, Quality, and Beyond-OCC cleared, not posting until 2021
- CDER: Hand Sanitizer--new content for FAQs on disinfectant tunnels; update to main FDA FAQs; internal reactive QA [SP link] **CDER - please confirm this is done - left the main FAQ update under likely today**
- SES: Stakeholder call – Arthritis Foundation
- SES: Stakeholder call – American College of Rheumatology
- Oncology listening session on COVID

SITREP ENDS

MEETING REPORT OUT (see Op Tempo for dial-in #s)

- Standing meetings updates (task forces, etc.)
- Hearings/Hill briefings
- NICCL calls (Tu/Th 10:15 a.m.)

MEDIA MONITORING

- See daily a.m. JIC email from Andrea Takash
- See NICCL JIC folder for social listening and other reports

###

April Finnen
IMG JIC Section Chief
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)
U.S. Food and Drug Administration
Cell: 240-507-7742 ←Call this # or IM/Skype to reach me
Email: april.finnen@fda.hhs.gov
JIC (Joint Information Center) leads email: 2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 6/15/2020 5:38:15 PM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: FW: WIRED Interview Request

FYSA.

Thanks,
Denise

From: Huckins, Grace <grace_huckins@wired.com>
Sent: Monday, June 15, 2020 5:10 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: WIRED Interview Request

Dear Admiral Hinton,

My name is Grace Huckins, and I am a writer on WIRED's science desk. I am currently working on a story about the FDA's revocation of the EUA for hydroxychloroquine, and I was hoping that you might be available for comment. If you are free to talk for about ten minutes any time before 10 AM PST tomorrow, it would be greatly appreciated. You can reach me at 650-785-8539.

Thank you so much for your time,

Grace

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 6/15/2020 4:53:31 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

I want

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, June 15, 2020 4:18 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

If u want – no big deal to me – just letting u know

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, June 15, 2020 4:17 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

Will do some reconnaissance….

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, June 15, 2020 3:25 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

Not so far as I know – request for Commis to call passed along and he made call – all he said was "call made"

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, June 15, 2020 3:24 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

Does Tom have any details?

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, June 15, 2020 3:22 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: FW: Please Call Dr. Peter Navarro at (b) (6)

Wonder if was related to revocation of CQ/HCQ EUA…

From: Allen, Henry <Henry.Allen@fda.hhs.gov>
Sent: Monday, June 15, 2020 12:36 PM
To: Russo, Mark <Mark.Russo@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Mignone, Alfred <Alfred.Mignone@fda.hhs.gov>
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

Hi Everyone:

Thanks for your help and suggestions.

I left a VM with Janice Sheehy and spoke with Frank Olivarria.

Very respectfully,

LCDR Henry Allen, USPHS
Manager, Emergency Operations Center (EOC)
COVID-19 FDA Incident Management Group (IMG)
Office of Emergency Operations
Office of Emergency Management
U.S. Food and Drug Administration
Desk: 301-796-8444
Cell: (b) (6)
Fax: 301-847-8543
Email: henry.allen@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 12:29 PM
To: Allen, Henry <Henry.Allen@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; Simms, Joshua <Joshua.Simms@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: Re: Please Call Dr. Peter Navarro at (b) (6)

Call made. Thanks
Steve

From: "Allen, Henry" <Henry.Allen@fda.hhs.gov>
Date: Monday, June 15, 2020 at 12:17 PM
To: Stephen Hahn <SH1@fda.hhs.gov>
Cc: Keagan Lenihan <Keagan.Lenihan@fda.hhs.gov>, Mark Russo <Mark.Russo@fda.hhs.gov>, Lionel Carter <Lionel.Carter@fda.hhs.gov>, "Simms, Joshua" <Joshua.Simms@fda.hhs.gov>, Janice Sheehy <Janice.Sheehy@fda.hhs.gov>, Frank Olivarria <Frank.Olivarria@fda.hhs.gov>
Subject: RE: Please Call Dr. Peter Navarro at (b) (6)

Adding Janice Sheehy and Frank Olivarria.

Very respectfully,

LCDR Henry Allen, USPHS
Manager, Emergency Operations Center (EOC)
COVID-19 FDA Incident Management Group (IMG)
Office of Emergency Operations
Office of Emergency Management
U.S. Food and Drug Administration
Desk: 301-796-8444
Cell: (b) (6)

Fax: 301-847-8543
Email: henry.allen@fda.hhs.gov
24 hour Emergency Number: 1-866-300-4374

U.S. FOOD & DRUG ADMINISTRATION

From: Allen, Henry
Sent: Monday, June 15, 2020 12:08 PM
To: SH1@fda.hhs.gov
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Russo, Mark <Mark.Russo@fda.hhs.gov>; Carter, Lionel <Lionel.Carter@fda.hhs.gov>; 'CAPT Joshua Simms' <Joshua.Simms@fda.hhs.gov>
Subject: Please Call Dr. Peter Navarro at (b) (6)
Importance: High

Dr Hahn:

I am the FDA Late Duty Officer this week and just received a call via the White House Situation Room.

Please call Dr. Peter Navarro at (b) (6) once you're off the phone with Dr. Birks.

This call was relayed through the White House Situation Room - Melissa Pomala – (b) (6)

The requestor was Joanna Miller - (b) (6) . – calling on behalf of Dr. Peter Navarro - (b) (6)

Very respectfully,

LCDR Henry Allen, USPHS
Emergency Operations Center (EOC) Manager
COVID-19 FDA Incident Management Group (IMG)
FDA Late Duty Officer
Office of Emergency Operations
Office of Emergency Management
U.S. Food and Drug Administration
Desk: 301-796-8444
Cell: (b) (6)
Fax: 301-847-8543
Email: henry.allen@fda.hhs.gov
24-hour Emergency Number: 1-866-300-4374

U.S. FOOD & DRUG ADMINISTRATION

From: Hinton, Denise [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=85FECA0BE0694803BE6030E97C7B4ADB-HINTOND]
Sent: 6/8/2020 2:21:57 PM
To: Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]
Subject: RE: does the Commish know

No details – will call you later today….

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, June 8, 2020 2:04 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: RE: does the Commish know

Assuming there r no issues or concerns…?

From: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Sent: Monday, June 8, 2020 1:04 PM
To: Mair, Michael <Michael.Mair@fda.hhs.gov>
Subject: RE: does the Commish know

Yes but said he'll circle back - no details

From: Mair, Michael <Michael.Mair@fda.hhs.gov>
Sent: Monday, June 8, 2020 12:57 PM
To: Hinton, Denise <Denise.Hinton@fda.hhs.gov>
Subject: does the Commish know

About the HCQ/CQ EUA revocation?

From: Emery, John [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C68B7BBB994D48FDB2F6F6802BFDB605-JOHN.EMERY]

Sent: 7/7/2020 3:43:39 PM

To: Baumgartner, Kristofer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f49b4b6cfcf4d249f8b1802a2c7dc40-BAUMGARTNER]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; Sykes, LaShawn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95f500b32a404714b1ec349f9d002c4c-Lashawn.Syk]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Morin, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e7ada1e856e450989eca925efcf201a-MORINS]; Cooper, Mildred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa838567ff8147ffb5933a8a698133b0-Mildred.Coo]; Wohl, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ee6d17fe8114d16bc6244f59d9d00b4-Alexander.W]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Leggin, Brooke

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; ODonnell, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0cdfec112cf4f558f9650bc5591a898-Allison.ODo]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Elicker, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88e18144ad424b8398b1fdfe85f6de5b-JElicker]; Roberts, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c09da5d79049fb902729d7e8328a34-Michelle.Ro]; Luebke, Yasemin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

CC: Lee, Marguerite [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6e40a857adef4a7587b71992d79809e0-Marguerite.]; Wanke, Hilary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3595b19b65eb4cdcb19e5c4f7dc11706-Hilary.Wank]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Litigation Hold [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4ae774ddb5d84977aac503990e4b3710-Litigation]; OP Policy Review Team [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=880566a7249e4495973f6957997d7031-OP Policy R]; Williams, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=63c605573234410491fad54cde597ecd-Susan.Willi]

Subject: ACTION REQUIRED: Retention of records relating to EUA for HCQ/CCQ

All:

Please be advised that a lawsuit has been filed in the United States District Court for the Western District of Michigan challenging the now-revoked emergency use authorization (EUA) for hydroxychloroquine sulfate and chloroquine phosphate (HCQ/CQ). The suit was filed by the Association of American Physicians and Surgeons against FDA, Commissioner Hahn, the Biomedical Advanced Research and Development Authority (BARDA), Acting Director Disbrow, the Department of Health and Human Services, and Secretary Azar. The Plaintiff makes allegations about the circumstances surrounding the issuance and revocation of the EUA and the HCQ in the Strategic National Stockpile (SNS). Plaintiff asks the court to order the Defendants to distribute HCQ from the stockpile promptly to members of the public who have valid prescriptions and to enjoin the Defendants from placing any restrictions on HCQ .

While this litigation is pending, the agency is under an obligation to retain documents and communications, including emails and other electronically stored information, that are potentially relevant to the case. Such documents and communications include, but are not limited to:

Documents, electronically stored information, and tangible items that were considered, directly or indirectly, during the decision-making process in connection with the request for and issuance of the

EUA, the request for and revocation of the EUA, the donation of HCQ to the SNS, and the disposition of HCQ from the SNS after the EUA was revoked.

During the course of any lawsuit, the opposing party may use the discovery process to obtain agency records about the allegations related to the case. The law requires FDA to preserve such information in whatever form it is generated and maintained. Therefore, the agency requires your assistance to preserve documents and other evidence, including electronic data, in connection with the subject of these lawsuits.

As an FDA employee, you are required to preserve all documents and data related to the subject of these lawsuits, including information stored in hard copy, on computer systems, on removable or portable electronic storage media, and on your personal computer, if used to create agency records. All electronically stored data, including e-mails and other electronic communication, word processing documents, spreadsheets, databases, calendars, telephone voice mails, and other kinds of media, must be retained until resolution of this matter. In addition, you must retain non-electronic documents and evidence in whatever form, including personal or desk files, calendars, notes, correspondence, and other things relevant to the case. Any routine data destruction policies related to these records must be discontinued until further notice from me.

You do not need to collect and produce the documents/electronic data at this time; rather, we are only seeking to preserve and prevent the destruction of existing information. Failure to preserve and retain information may result in sanctions against the agency. Consequently, if you are unsure whether certain information should be preserved, err on the side of caution and preserve the information until you have discussed the issue with [indicate who should be contacted]. If production of some or all of the material is required at a later date, you will receive further instructions from an attorney assigned to this matter. Also, if you have any questions about how to preserve electronically stored information, please contact me.

Although you are not required to collect documents/electronic data at this time, where possible, it is advisable to segregate potentially relevant information. This can help ensure it is not inadvertently destroyed (e.g., by operation of an electronic system or according to prior record retention policies) and can facilitate ease of retrieval if production becomes necessary.

In addition, please make sure that this message is distributed to all personnel in your office who may be involved in, or have information pertaining to, this lawsuit. Because this message is confidential, however, do not send it outside the agency without first discussing it with me or an attorney from my office. **Please send me the names of the people to whom you forward this message**. I also advise that you document the specific actions taken by you and your office in response to this message.

If you or your office have in your possession, custody, or control any documents/electronic data within the category described above, or if you are responsible for an office that has any documents/electronic data, you must preserve and retain the information through the time that you are either instructed to collect it or informed that the preservation instruction is no longer in effect. As stated above, no documents/electronic data need be collected or produced at this point.

Please click the "yes" voting button above to confirm that you have received this notice, understand your obligations, and agree to comply with the instructions.

If you have any questions about your obligations to preserve information, please contact Susan Williams at Susan.Williams@fda.hhs.gov.

From: Anand.Shah@fda.hhs.gov [Anand.Shah@fda.hhs.gov]
Sent: 6/24/2020 5:30:13 PM
To: Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: Re: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Let me check on the date - will come back to you - this was set up by OEA. It would be great to have SME from CDER.

On Jun 24, 2020, at 17:01, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov> wrote:

When is this planned for and will you need anyone from CDER to participate?
Patrizia

From: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Sent: Wednesday, June 24, 2020 4:56 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Subject: FW: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today
Importance: High

Hi Dr. Cavazzoni,

CDER was asked to review these talking points regarding the HCQ/CQ EUA revocation.

OND-Policy, OID, OMP and ORP have all edited and cleared the talking points – their edits and comments are in SharePoint. We wanted to allow you the chance to look at their edits before stating they are CDER cleared. They're due at 6pm today.

http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/SH%20talking%20points/2020-06-26%20Shah%20remarks%20for%20stakeholder%20call%20on%20HQ.1.docx

Many thanks,
Kristen

From: Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
Sent: Wednesday, June 24, 2020 10:08 AM
To: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>; 2019-nCoV FDA IMG JIC Leadership <2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov>
Cc: Fritsch, Beth F. <Beth.Fritsch@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Good morning JIC CDER and JIC Leadership teams,

Attached for your review and comments are draft opening remarks to be given by Dr. Shah to an upcoming stakeholder call with the autoimmune community to explain the scientific basis behind the revocation of emergency use authorizations for chloroquine and hydroxychloroquine.

If you could provide your edits and comments by 6 pm this evening that would be greatly appreciated. Please make any edits in the SharePoint document below:

http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/SH%20talking%20points/2020-06-26%20Shah%20remarks%20for%20stakeholder%20call%20on%20HQ.1.docx

Thanks,

Alex

ALEX WOHL, J.D. |
WRITER-EDITOR; SPEECHWRITER
Office of Editorial and Creative Services | Office of External Affairs
U.S. Food and Drug Administration
w: 240-402-0363 | m: 202-573-2344

From: (b) (6), (b) (4)
Sent: 7/6/2020 2:24:43 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: HCQ EUA Revocation

Hi Dr Shah

Is the FDA planning to re-instate the EUA for HCQ in light of the Henry Ford Hospital system study?

I feel that the revocation of the HCQ EUA on 6/15/20 was questionable, since it was apparently based on the VA-REACH study which included only 300 subjects, and the Oxford RECOVERY study which did not publish the protocol for the HCG arm of the trial.

Thank you

(b) (6), (b) (4)

From: Kadakia, Kushal [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A10A749D49F9473AA2CD046423EE61BD-KUSHAL.KADA]
Sent: 6/29/2020 4:10:45 PM
To: Hahn, Stephen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a0afac0cfa3c4b98913833e38a036e9f-Stephen.Hah]
CC: Zeta, Lowell [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9c0fc7eb68244f4cb4260898d5dacadb-Lowell.Zeta]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: GAO CARES Act Report -- Memo
Attachments: GAO CARES Report Memo_06.29.2020.docx

Hi Dr. Hahn,

Lowell & I drafted a memo summarizing the FDA-relevant information in the GAO's recent report on the CARES Act (attached). Let us know if you have any questions or need any additional information.

Best,
Kushal

Kushal Kadakia
Office of the Commissioner
+1 240 731-3885 | kushal.kadakia@fda.hhs.gov

MEMORANDUM

This memorandum provides a summary of the GAO report titled "Opportunities to Improve Federal Response and Recovery Efforts" issued to Congress on June 25, 2020, with regard to FDA's actions to address challenges during the COVID-19 pandemic.

Background

The CARES Act requires GAO to submit a report on its monitoring and oversight efforts related to the COVID-19 pandemic, with subsequent bimonthly reports through March 2021. The first report focuses on (1) the key actions the federal government has taken, (2) potential indicators for monitoring the public health system's preparedness, and (3) evolving lessons learned relevant to the nation's response.

The primary challenges highlighted in the report include CDC's incomplete and inconsistent reporting of viral testing, shortages of critical supplies, and potential for fraud in the paycheck protection program. GAO's recommendations are focused on SBA, IRS, DOL and DOT, and further recommendations may be issued based on GAO's ongoing work as described below.

FDA's Efforts and GAO's Ongoing Review

FDA's actions are discussed in connection with other federal partners' efforts and challenges with respect to the Strategic National Stockpile (SNS), COVID-19 testing, and vaccine development.

Below is a summary of the FDA's actions cited in the report and issues that GAO is continuing to review:

- SNS: When describing the depletion of the stockpile's resources, GAO references the FDA's issuance and revocation of the EUA for hydroxychloroquine, and FDA's EUA for remdesivir. The GAO states that it is conducting a comprehensive body of work on the SNS which will include examining state requests, purchasing decisions, and restructuring the SNS based on lessons learned.

- COVID-19 Testing: When describing delays and reporting gaps in COVID-19 testing, GAO addresses FDA's policy changes to increase testing capacity in response to concerns around accuracy and reliability issues associated with the CDC-deployed test. In addition, GAO noted that FDA has limited authority to address supply shortages for testing, but took steps to encourage increased manufacturing of supplies, *e.g.*, swabs and transport media. GAO states that it will continue to conduct work examining HHS and its component agencies' roles with regard to testing.

- Vaccine Development: GAO references COVID-19 appropriations for the development of medical countermeasures and vaccines, and notes the FDA's participation in the ACTIV partnership and creation of CTAP. GAO clarifies the scope of EUA authority and provides a summary of active trials and development programs for therapeutics. GAO plans to conduct further work on federal efforts to accelerate and coordinate development and testing of vaccines and therapeutics, and the process and policies related to their development, approval, and distribution.

- Food Safety: GAO indicates that it will explore FDA's response on food safety during COVID-19, and notes that the CARES Act did not appropriate supplemental funds for inspections.

Although FDA was not a significant focus of the June 25 report, it is likely that the agency will receive additional requests for information for subsequent reports. Testing and vaccine development, supply chain resiliency, and food safety are likely to be relevant topics where FDA will need to provide further information.

From: Kadakia, Kushal [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=A10A749D49F9473AA2CD046423EE61BD-KUSHAL.KADA]
Sent: 6/28/2020 9:24:35 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Yes will do

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Sunday, June 28, 2020 11:09 AM
To: Kadakia, Kushal <Kushal.Kadakia@fda.hhs.gov>
Subject: FW: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

(b) (5)

From: Shah, Anand
Sent: Thursday, June 25, 2020 10:19 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Thanks Patrizia. +Dayle here for logistical details on the event
Anand

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 24, 2020 5:56 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Thank you. I just cleared the TPs for CDER. I will look at the final version when ready (b) (5)

Patrizia

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 24, 2020 5:30 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: Re: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Let me check on the date - will come back to you - this was set up by OEA. (b) (5)

On Jun 24, 2020, at 17:01, Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov> wrote:

When is this planned for and will you need anyone from CDER to participate?
Patrizia

From: Booze, Kristen <Kristen.Booze@fda.hhs.gov>
Sent: Wednesday, June 24, 2020 4:56 PM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Cc: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Subject: FW: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today
Importance: High

Hi Dr. Cavazzoni,

CDER was asked to review these talking points regarding the HCQ/CQ EUA revocation.

OND-Policy, OID, OMP and ORP have all edited and cleared the talking points – their edits and comments are in SharePoint. We wanted to allow you the chance to look at their edits before stating they are CDER cleared. They're due at 6pm today.

http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/SH%20talking%20points/2020-06-26%20Shah%20remarks%20for%20stakeholder%20call%20on%20HQ.1.docx

Many thanks,
Kristen

From: Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>
Sent: Wednesday, June 24, 2020 10:08 AM
To: 2019-nCoV FDA IMG JIC CDER <2019-nCoVFDAIMGJICCDER@fda.hhs.gov>; 2019-nCoV FDA IMG JIC Leadership <2019-nCoV-FDA-IMG-JIC-Leadership@fda.hhs.gov>
Cc: Fritsch, Beth F. <Beth.Fritsch@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: Review requested of remarks for Dr. Shah on chloroquine and Hydroxychloroquine -- BY 6 pm today

Good morning JIC CDER and JIC Leadership teams,

Attached for your review and comments are draft opening remarks to be given by Dr. Shah to an upcoming stakeholder call with the autoimmune community to explain the scientific basis behind the revocation of emergency use authorizations for chloroquine and hydroxychloroquine.

If you could provide your edits and comments by 6 pm this evening that would be greatly appreciated. Please make any edits in the SharePoint document below:

http://sharepoint.fda.gov/orgs/OC-OCET/OCETdocs/nCoV/Shared%20Documents/SH%20talking%20points/2020-06-26%20Shah%20remarks%20for%20stakeholder%20call%20on%20HQ.1.docx

Thanks,

Alex

ALEX WOHL, J.D. |
WRITER-EDITOR; SPEECHWRITER
Office of Editorial and Creative Services | Office of External Affairs
U.S. Food and Drug Administration
w: 240-402-0363 | m: (b) (6)

From: Lenihan, Keagan [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=EE7320EE8C184D66BFD521B0105D17D2-KEAGAN.LENI]
Sent: 6/19/2020 4:05:48 PM
To: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]
Subject: RE: Comms Touch Base: HCQ

No problem.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Friday, June 19, 2020 3:25 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Will definitely do – and thanks for the feedback this afternoon

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, June 19, 2020 2:29 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: Comms Touch Base: HCQ

FYSA – lets work with CDER on the front end of things so we don't run into this issue. Pls reach out directly to Patrizia on initial asks and she will help figure out the best way to put the info together.

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, June 19, 2020 12:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5)
[redacted]
Patrizia

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Thursday, June 18, 2020 6:44 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Don,

Here is the document with Dr. Cavazzoni edits and ORP's. Please let me know if you need anything further for your review.

Thanks,
Chris

From: Shreeve, Chris
Sent: Wednesday, June 17, 2020 5:08 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Don. We will get it through CDER as quickly as possible and then back to you.

Chris

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 4:42 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Chris,

I am glad to give my feedback now, but it would probably be good for me to look again if there are further revisions. I have a couple of comments with potential edits on the last page of the attached.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Hi,

Just checking. Has this gone through CDER or will it go there after Don clears? Thanks!

Chris

Chris Shreeve
Director, Office of Communications

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-5772
chris.shreeve@fda.hhs.gov

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

No problem – looping in Don Beers as well, here is a first draft for review.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Jeet.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:07 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(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: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:57 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Adding Chris Shreeve, who can make sure this goes through CDER clearance, DAV in particular since they wrote the memo. I recommend that Don Beers also review.
Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:53 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Attaching the document as well

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

+Patrizia and Mary Beth for awareness. Jeet will be reaching out to CDER shortly to help pull it all together
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:39 AM

To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Totally agree – we will build all this in and send a revised version shortly

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) [redacted]

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:29 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

All good feedback. Would like to emphasize that we do not regulate the (b) (5) [redacted]

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:26 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle

<Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

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

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:21 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

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

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Great, thanks for the clarification. let's get feedback from this group and then we can circulate wider

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:02 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks – just to clarify this has not been reviewed by CDER yet

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael

<Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Moving Steve to bcc

Dear All –

Following up from yesterday's discussion, Jeet worked with CDER on a proposed statement that provides scientific rationale for our decision.

We welcome your feedback.

Thank you

Anand

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 9:44 PM
To: Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Caliguiri, Laura; Rebello, Heidi; Caccomo, Stephanie; Felberbaum, Michael; Pines, Wayne *
Subject: Comms Touch Base: HCQ
When: Tuesday, June 16, 2020 8:15 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6)

From: Shreeve, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=571674B26CA64F578288F39264470299-CHRISTINE.K]
Sent: 6/18/2020 8:51:53 PM
To: Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
CC: Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: RE: Comms Touch Base: HCQ

Thank you.

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Thursday, June 18, 2020 7:27 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks, Chris. (b) (5) If there are further changes before finalization, I guess I should look again.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Thursday, June 18, 2020 6:44 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne *

<Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Don,

Here is the document with Dr. Cavazzoni edits and ORP's. Please let me know if you need anything further for your review.

Thanks,
Chris

From: Shreeve, Chris
Sent: Wednesday, June 17, 2020 5:08 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Don. We will get it through CDER as quickly as possible and then back to you.

Chris

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 4:42 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Chris,

I am glad to give my feedback now, but it would probably be good for me to look again if there are further revisions. I have a couple of comments with potential edits on the last page of the attached.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Hi,

Just checking. Has this gone through CDER or will it go there after Don clears? Thanks!

Chris

Chris Shreeve
Director, Office of Communications

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-5772
chris.shreeve@fda.hhs.gov

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

No problem – looping in Don Beers as well, here is a first draft for review.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Jeet.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:07 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>

Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Sounds good – I'll take a stab at adding info on what the original EUA meant, the data that was used to make the decision to revoke the EUA, and what the revocation did and didn't mean, and then I'll send the document back around to this group plus Don Beers.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:57 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Adding Chris Shreeve, who can make sure this goes through CDER clearance, DAV in particular since they wrote the memo. I recommend that Don Beers also review.
Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:53 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Attaching the document as well

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

+Patrizia and Mary Beth for awareness. Jeet will be reaching out to CDER shortly to help pull it all together
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:39 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Totally agree – we will build all this in and send a revised version shortly

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) [redacted]

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:29 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

All good feedback. Would like to emphasize that we do not regulate (b) (5) [redacted]

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:26 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

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

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:21 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) (b) (5)
. I took a quick stab at rearranging a bit.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Great, thanks for the clarification. let's get feedback from this group and then we can circulate wider

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:02 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks – just to clarify this has not been reviewed by CDER yet

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration

+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Moving Steve to bcc

Dear All –

Following up from yesterday's discussion, Jeet worked with CDER on a proposed statement that provides scientific rationale for our decision.

We welcome your feedback.

Thank you

Anand

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 9:44 PM
To: Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Caliguiri, Laura; Rebello, Heidi; Caccomo, Stephanie; Felberbaum, Michael; Pines, Wayne *
Subject: Comms Touch Base: HCQ
When: Tuesday, June 16, 2020 8:15 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6)

From: Shreeve, Chris [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=571674B26CA64F578288F39264470299-CHRISTINE.K]
Sent: 6/18/2020 11:53:01 AM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
CC: Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]
Subject: RE: Comms Touch Base: HCQ

Just want you to know that this is in CDER clearance and we hope to have it to Don later today.

Chris

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 4:42 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Chris,

I am glad to give my feedback now, but it would probably be good for me to look again if there are further revisions. I have a couple of comments with potential edits on the last page of the attached.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>

Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Hi,

Just checking. Has this gone through CDER or will it go there after Don clears? Thanks!

Chris

Chris Shreeve
Director, Office of Communications

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-5772
chris.shreeve@fda.hhs.gov

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

No problem – looping in Don Beers as well, here is a first draft for review.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Jeet.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:07 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(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: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:57 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Adding Chris Shreeve, who can make sure this goes through CDER clearance, DAV in particular since they wrote the memo. I recommend that Don Beers also review.
Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:53 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Attaching the document as well

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

+Patrizia and Mary Beth for awareness. Jeet will be reaching out to CDER shortly to help pull it all together
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:39 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Totally agree – we will build all this in and send a revised version shortly

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5)
[redacted]

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:29 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>;

Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

All good feedback. Would like to emphasize that we do not regulate the (b) (5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:26 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) ɔ) (5)

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:21 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) (b) (5)
. I took a quick stab at rearranging a bit.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Great, thanks for the clarification. let's get feedback from this group and then we can circulate wider

---

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:02 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne *

<Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks – just to clarify this has not been reviewed by CDER yet

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Moving Steve to bcc

Dear All –

Following up from yesterday's discussion, Jeet worked with CDER on a proposed statement that provides scientific rationale for our decision.

We welcome your feedback.

Thank you

Anand

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 9:44 PM
To: Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Caliguiri, Laura; Rebello, Heidi; Caccomo, Stephanie; Felberbaum, Michael; Pines, Wayne *
Subject: Comms Touch Base: HCQ
When: Tuesday, June 16, 2020 8:15 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6)

From: Beers, Donald [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D079BF15A01744BD94687D6718CA4C42-DONALD.BEER]
Sent: 6/17/2020 5:46:15 PM
To: Clarke, Mary Beth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b0124a15b9344d8483929470fefa403a-CLARKEM]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]
CC: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Cavazzoni, Patrizia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c42abd33834044ecbaa03d075cc0a5d2-Patrizia.Ca]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: RE: Comms Touch Base: HCQ

Mary Beth,

(b) (5)

Don

From: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 5:34 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5)

Mary Beth

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 5:08 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>

Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Don. We will get it through CDER as quickly as possible and then back to you.

Chris

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 4:42 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Chris,

I am glad to give my feedback now, but it would probably be good for me to look again if there are further revisions. I have a couple of comments with potential edits on the last page of the attached.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Hi,

Just checking. Has this gone through CDER or will it go there after Don clears? Thanks!

Chris

Chris Shreeve
Director, Office of Communications

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-5772
chris.shreeve@fda.hhs.gov

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

No problem – looping in Don Beers as well, here is a first draft for review.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Jeet.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:07 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(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: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:57 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Adding Chris Shreeve, who can make sure this goes through CDER clearance, DAV in particular since they wrote the memo. I recommend that Don Beers also review.
Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:53 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Attaching the document as well

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

+Patrizia and Mary Beth for awareness. Jeet will be reaching out to CDER shortly to help pull it all together
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:39 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Totally agree – we will build all this in and send a revised version shortly

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) [redacted]

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:29 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

All good feedback. Would like to emphasize that we do not regulate the (b) (5) [redacted]

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:26 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) ɔ) (5) [redacted]

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:21 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) (b) (5)
. I (b) (5)

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Great, thanks for the clarification. let's get feedback from this group and then we can circulate wider

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:02 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks – just to clarify this has not been reviewed by CDER yet

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Moving Steve to bcc

Dear All –

Following up from yesterday's discussion, Jeet worked with CDER on a proposed statement that provides scientific rationale for our decision.

We welcome your feedback.

Thank you

Anand

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 9:44 PM
To: Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Caliguiri, Laura; Rebello, Heidi; Caccomo, Stephanie; Felberbaum, Michael; Pines, Wayne *
Subject: Comms Touch Base: HCQ
When: Tuesday, June 16, 2020 8:15 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6)

From: Felberbaum, Michael [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4819A643CA2945CDB1A2631B83E69673-MICHAEL.FEL]
Sent: 6/16/2020 6:18:46 PM
To: Amin, Stacy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=cb3764b7438648838c22881a06fc6afb-Stacy.Amin]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
Subject: RE: FLAGGING -- NYT on HCQ

Shared the response with the reporter. Told we should expect the story to go online tonight. Will flag when I see.

From: Felberbaum, Michael
Sent: Tuesday, June 16, 2020 4:48 PM
To: Amin, Stacy <Stacy.Amin@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FLAGGING -- NYT on HCQ

Thanks. Will let you know if I hear anything different from ASPA.

From: Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Sent: Tuesday, June 16, 2020 4:03 PM
To: Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Subject: RE: FLAGGING -- NYT on HCQ

(b) (5) is ok with me.

From: Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Sent: Tuesday, June 16, 2020 4:02 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: FLAGGING -- NYT on HCQ

I would just suggest (b) (5)

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Date: June 16, 2020 at 3:45:49 PM EDT
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>, Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>, Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>, Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>, Pines, Wayne * <Wayne.Pines@fda.hhs.gov>, Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: FLAGGING -- NYT on HCQ

I am good with it. Others?

Sent from my iPhone

On Jun 16, 2020, at 3:42 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

OK to send back?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, June 16, 2020 3:21 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: FLAGGING -- NYT on HCQ

Thx

Sent from my iPhone

On Jun 16, 2020, at 2:53 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Here's the proposed response to the outstanding Q: *Secretary*(b) (5)

From: Felberbaum, Michael
Sent: Tuesday, June 16, 2020 1:13 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: FLAGGING -- NYT on HCQ

INTERNAL – DELIBERATIVE – CONFIDENTIAL

Hi both,

NYT is reviving the story it was looking to do a month or so ago about CQ/HCQ EUA – how it came to be, and now the revocation. We should expect the story in the next day or so. Stacy, just flagging given this was the reporter you spoke with previously, there will likely be mention of the emails from the Bright complaint. The reporter has all of the previous comment/background we'd provided, which still stands, and ASPR had provided them comment/information as well. I don't expect the story to be anything we haven't already seen written on this topic and as we noted, there have been a number of comments, etc. provided to the reporter.

The reporter has followed up with a couple of specific questions (one which was answered by our online QA) but the remaining Q is(b) (5) ? For awareness, the reporter also noted that in an interview with her, Peter Navarro called this an action of "the deep state."

ASPA is aware and I will circle back.

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

<image002.png>

<image004.jpg>

<image006.jpg>

<image008.jpg>

<image010.jpg>

<image012.jpg>

From: Amin, Stacy [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CB3764B7438648838C22881A06FC6AFB-STACY.AMIN]
Sent: 6/16/2020 4:01:59 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]
CC: Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]
Subject: RE: FLAGGING -- NYT on HCQ

Fine here.

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, June 16, 2020 3:46 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: FLAGGING -- NYT on HCQ

I am good with it. Others?

Sent from my iPhone

On Jun 16, 2020, at 3:42 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

OK to send back?

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Tuesday, June 16, 2020 3:21 PM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Cc: Shah, Anand <Anand.Shah@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: Re: FLAGGING -- NYT on HCQ

Thx

Sent from my iPhone

On Jun 16, 2020, at 2:53 PM, Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov> wrote:

Here's the proposed response to the outstanding Q: (b) (5)

From: Felberbaum, Michael
Sent: Tuesday, June 16, 2020 1:13 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Amin, Stacy <Stacy.Amin@fda.hhs.gov>
Subject: FLAGGING -- NYT on HCQ

INTERNAL – DELIBERATIVE – CONFIDENTIAL

Hi both,

NYT is reviving the story it was looking to do a month or so ago about CQ/HCQ EUA – how it came to be, and now the revocation. We should expect the story in the next day or so. Stacy, just flagging given this was the reporter you spoke with previously, there will likely be mention of the emails from the Bright complaint. The reporter has all of the previous comment/background we'd provided, which still stands, and ASPR had provided them comment/information as well. I don't expect the story to be anything we haven't already seen written on this topic and as we noted, there have been a number of comments, etc. provided to the reporter.

The reporter has followed up with a couple of specific questions (one which was answered by our online QA) but the remaining Q (b) (5) ? For awareness, the reporter also noted that in an interview with her, Peter Navarro called this an action of "the deep state."

ASPA is aware and I will circle back.

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

<image002.png>

<image004.jpg>

<image006.jpg>

<image008.jpg>

<image010.jpg>

<image012.jpg>

From: Caccomo, Stephanie [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=950C32CEBC4B4F80B302C50CF31C8524-STEPHANIE.C]
Sent: 6/15/2020 11:13:30 AM
To: Elicker, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88e18144ad424b8398b1fdfe85f6de5b-JElicker]; Booze, Kristen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86338261bf6646c59bf8cf7c18d12de3-Kristen.Boo]; Baumgartner, Kristofer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f49b4b6cfcf4d249f8b1802a2c7dc40-BAUMGARTNER]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Finnen, April [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=43d74b30bb1d429184b0d9081efe19bf-April.Finne]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; Sykes, LaShawn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95f500b32a404714b1ec349f9d002c4c-Lashawn.Syk]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Morin, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e7ada1e856e450989eca925efcf201a-MORINS]; Cooper, Mildred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa838567ff8147ffb5933a8a698133b0-Mildred.Coo]; Wohl, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ee6d17fe8114d16bc6244f59d9d00b4-Alexander.W]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Klimczak, Katherine

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Van Pool, Kendall [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Leggin, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; ODonnell, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0cdfec112cf4f558f9650bc5591a898-Allison.ODo]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Roberts, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c09da5d79049fb902729d7e8328a34-Michelle.Ro]; Luebke, Yasemin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Leboeuf, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d35ec585598148118abdfd25f495c8f5-Andrew.Lebo]; Schumann, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e4251f58ae47b195422a2349b5e3ce-SCHUMANNK]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

CC: Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]

Subject: RE: Plan for tomorrow: HCQ

Thanks Jan. Resolving some last minute edits with HHS on PR. Will keep you posted on PR.

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: Elicker, Janet <Janet.Elicker@fda.hhs.gov>
Sent: Monday, June 15, 2020 11:08 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Baumgartner, Kristofer <Kristofer.Baumgartner@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Hunt,

Alison <Alison.Hunt@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Sykes, LaShawn <LaShawn.Sykes@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Morin, Steve <Steve.Morin@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; ODonnell, Allison <Allison.ODonnell@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: RE: Plan for tomorrow: HCQ

The revocation letter and FAQs are now posted:

Revocation letter w/ memo attached: https://www.fda.gov/media/138945/download
EUA FAQs: https://www.fda.gov/media/138946/download

Updated EUA page: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

Jan Elicker
OEA Web and Digital Services Staff
Web posting lead
Joint Information Center (JIC)
2019 Novel Coronavirus (COVID-19) Incident Management Group (IMG)
office: 301-796-8416
cell: (b) (6)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Sunday, June 14, 2020 8:31 PM
To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Baumgartner, Kristofer <Kristofer.Baumgartner@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Sykes, LaShawn <LaShawn.Sykes@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Morin, Steve <Steve.Morin@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Van Pool, Kendall

<Kendall.VanPool@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; ODonnell, Allison <Allison.ODonnell@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Elicker, Janet <Janet.Elicker@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: Plan for tomorrow: HCQ

Hi all!

To sum up policy rollout:

- (b) (5)
-
-

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b) (6)
stephanie.caccomo@fda.hhs.gov

-----Original Appointment-----
From: Caccomo, Stephanie
Sent: Sunday, June 14, 2020 1:33 PM
To: Caccomo, Stephanie; Booze, Kristen; Baumgartner, Kristofer (Kristofer.Baumgartner@fda.hhs.gov); Shreeve, Chris; Hunt, Alison; Tantillo, Andrew; Gross, Karas; McBride, Maren; Anderson, Erika; Finnen, April; Cristinzio, Dayle; Walsh, Sandy; Caliguiri, Laura; Rebello, Heidi; Lynch, Sarah; Black, Jennifer; Meister, Karen G; Alexander, Nicholas; Sykes, LaShawn; Kimberly, Brad; Schipper, Jodi; Morin, Steve; Cooper, Mildred; Wohl, Alexander; Mair, Michael (Michael.Mair@fda.hhs.gov); Sadove, Elizabeth (Elizabeth.Sadove@fda.hhs.gov); Guevara, Bessy; Klimczak, Katherine; Van Pool, Kendall; Leggin, Brooke; ODonnell, Allison; Pines, Wayne *; Elicker, Janet; Roberts, Michelle; Luebke, Yasemin; Hodnette, Jonathan; Campbell, Christopher; Leboeuf, Andrew; Schumann, Katherine; Walinsky, Sarah; Kraus, Stefanie; Beers, Donald; Raza, Mark; Lenihan, Keagan; Abram, Anna; Shah, Anand
Cc: Sipes, Grail; Farley, John
Subject: Quick check in on comms for tmrw--HCQ EUA
When: Sunday, June 14, 2020 8:00 PM-8:15 PM (UTC-05:00) Eastern Time (US & Canada).
Where: webex

INTERNAL DELIBERATIVE

Hi all—sorry to ping on a Sunday, but still lots of moving pieces. Let's try to put CDER SMEs plus agency comms folks on a call to nail down timing for tomorrow. Will cancel meeting if not needed.

Join by phone
(b) (6) US Toll
(b) (6) US Toll Free
Access code: (b) (6)

From: Finnen, April [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=43D74B30BB1D429184B0D9081EFE19BF-APRIL.FINNE]
Sent: 6/15/2020 7:41:25 AM
To: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Booze, Kristen [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=86338261bf6646c59bf8cf7c18d12de3-Kristen.Boo]; Baumgartner, Kristofer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8f49b4b6cfcf4d249f8b1802a2c7dc40-BAUMGARTNER]; Shreeve, Chris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=571674b26ca64f578288f39264470299-Christine.K]; Hunt, Alison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c0f683a75ebd4235abf90d887b5f7293-Alison.Hunt]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Gross, Karas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0b6d3dc4ee4b415d86ec634c536453b6-Kara.Gross]; McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Anderson, Erika [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=98606928b9a64edfb25aba1e3573fdfe-Eranders]; Cristinzio, Dayle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b5a8dc4e587946fa938714a962df4246-Dayle.Crist]; Walsh, Sandy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c61503c4e7884fc28b9ef6cb8f2514ec-Sandy.Walsh]; Caliguiri, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa086f2d6c0346c49e996932d86ac62e-Laura.Calig]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]; Lynch, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d24ee4a4fc6241f48110d6b35e6704ed-Sarah.Lynch]; Black, Jennifer [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aaf8a19f3672492293a7c1b2d1498059-Jennifer.Bl]; Meister, Karen G [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7f2cdcd99e784c6cb3e8bf491fee037f-KMEISTER]; Alexander, Nicholas [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08e1fd211c4a4c96be426218bd0711e9-Nicholas.Al]; Sykes, LaShawn [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=95f500b32a404714b1ec349f9d002c4c-Lashawn.Syk]; Kimberly, Brad [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=08bc909ed76d49868a5ff92c3c70fb72-Bradley.Kim]; Schipper, Jodi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2373b9ecd1654e65992a9a5fbee59630-SCHIPPERJ]; Morin, Steve [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e7ada1e856e450989eca925efcf201a-MORINS]; Cooper, Mildred [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=aa838567ff8147ffb5933a8a698133b0-Mildred.Coo]; Wohl, Alexander [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3ee6d17fe8114d16bc6244f59d9d00b4-Alexander.W]; Mair, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f4511bdad7564d7fac7eadc7961467ab-Michael.Mai]; Sadove, Elizabeth [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fd45c627000d4f34b9db362ff2b6af4b-SADOVEE]; Guevara, Bessy [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58097ba8edea47afb3338e671a43dc04-Bessy.Gueva]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]; Van Pool, Kendall

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=db264f9a066044fc82aca6b12698467e-Kendall.Van]; Leggin, Brooke [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c876a439c57d4d0abaa3c8898c803db3-Brooke.Legg]; ODonnell, Allison [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d0cdfec112cf4f558f9650bc5591a898-Allison.ODo]; Pines, Wayne * [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0e9f5ce0254041a48966c10d0c38bef5-Wayne.Pines]; Elicker, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=88e18144ad424b8398b1fdfe85f6de5b-JElicker]; Roberts, Michelle [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e1c09da5d79049fb902729d7e8328a34-Michelle.Ro]; Luebke, Yasemin [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=10d526e5c46f47ce83978507a5365de5-Yasemin.Lue]; Hodnette, Jonathan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eea0ff4c9fe6418ea8bf16a891db85b9-Jonathan.Ho]; Campbell, Christopher [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8e72b376d4a54dd08fc0f7ae915401d4-Christopher]; Leboeuf, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d35ec585598148118abdfd25f495c8f5-Andrew.Lebo]; Schumann, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c3e4251f58ae47b195422a2349b5e3ce-SCHUMANNK]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Kraus, Stefanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9d3959f3365b4fc39a7eb324539215bc-Stefanie.Kr]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]; Abram, Anna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fb77660891384232a7cd9086fcbb1a3b-Anna.Abram]; Shah, Anand [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e2172ebbd96946c08e189fd612855f51-Anand.Shah]

CC: Sipes, Grail [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ccee8d18ee1f4a36885078f780c2f2f8-SIPESG]; Farley, John [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d9dc8109c3ea49ed8f897ac979b0619b-FARLEYJ]

Subject: RE: Rollout Email for HCQ

Jan Elicker created a placeholder for the revocation letter link:
https://www.fda.gov/media/138945/download

Will replace w/actual letter PDF as soon as available.

Other OCET pages that will be updated today, on greenlight:

- EUA page – current EUAs
- EUA archive page – terminated EUAs (new COVID section)

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Monday, June 15, 2020 7:36 AM
To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Baumgartner, Kristofer <Kristofer.Baumgartner@fda.hhs.gov>;

Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Sykes, LaShawn <LaShawn.Sykes@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Morin, Steve <Steve.Morin@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Mair, Michael <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; ODonnell, Allison <Allison.ODonnell@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Elicker, Janet <Janet.Elicker@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: Rollout Email for HCQ

Hi all—
Just flagging the rollout email so we are all in awareness. Please send all updates to this. April/Jan/Kristen—please send weblinks here so we can all see.

Thanks!!

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b) (6)
stephanie.caccomo@fda.hhs.gov

From: Caccomo, Stephanie
Sent: Sunday, June 14, 2020 8:31 PM
To: Booze, Kristen <Kristen.Booze@fda.hhs.gov>; Baumgartner, Kristofer (Kristofer.Baumgartner@fda.hhs.gov) <Kristofer.Baumgartner@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Gross, Karas <Karas.Gross@fda.hhs.gov>; McBride, Maren <Maren.McBride@fda.hhs.gov>; Anderson, Erika <Erika.Anderson@fda.hhs.gov>; Finnen, April <April.Finnen@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Lynch, Sarah <Sarah.Lynch@fda.hhs.gov>; Black, Jennifer <Jennifer.Black@fda.hhs.gov>; Meister, Karen G <Karen.Meister@fda.hhs.gov>; Alexander, Nicholas <Nicholas.Alexander@fda.hhs.gov>; Sykes, LaShawn <LaShawn.Sykes@fda.hhs.gov>; Kimberly, Brad <Brad.Kimberly@fda.hhs.gov>; Schipper, Jodi <jodi.schipper@fda.hhs.gov>; Morin, Steve <Steve.Morin@fda.hhs.gov>; Cooper, Mildred <Mildred.Cooper@fda.hhs.gov>; Wohl, Alexander <Alexander.Wohl@fda.hhs.gov>; Mair, Michael (Michael.Mair@fda.hhs.gov) <Michael.Mair@fda.hhs.gov>; Sadove, Elizabeth (Elizabeth.Sadove@fda.hhs.gov) <Elizabeth.Sadove@fda.hhs.gov>; Guevara, Bessy <Bessy.Guevara@fda.hhs.gov>; Klimczak, Katherine

<Katherine.Klimczak@fda.hhs.gov>; Van Pool, Kendall <Kendall.VanPool@fda.hhs.gov>; Leggin, Brooke <Brooke.Leggin@fda.hhs.gov>; ODonnell, Allison <Allison.ODonnell@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Elicker, Janet <Janet.Elicker@fda.hhs.gov>; Roberts, Michelle <Michelle.Roberts1@fda.hhs.gov>; Luebke, Yasemin <Yasemin.Luebke@fda.hhs.gov>; Hodnette, Jonathan <Jonathan.Hodnette@fda.hhs.gov>; Campbell, Christopher <Christopher.Campbell@fda.hhs.gov>; Leboeuf, Andrew <Andrew.Leboeuf@fda.hhs.gov>; Schumann, Katherine <Katherine.Schumann@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Kraus, Stefanie <Stefanie.Kraus@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Abram, Anna <Anna.Abram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>
Cc: Sipes, Grail <Grail.Sipes@fda.hhs.gov>; Farley, John <John.Farley@fda.hhs.gov>
Subject: Plan for tomorrow: HCQ

Hi all!

To sum up policy rollout:

- (b) (5)
-
-

Stephanie Caccomo
Press Officer

Office of Media Affairs
Office of External Affairs
U.S. Food and Drug Administration
Desk: 301.348.1956
Cell: (b) (6)
stephanie.caccomo@fda.hhs.gov

-----Original Appointment-----
From: Caccomo, Stephanie
Sent: Sunday, June 14, 2020 1:33 PM
To: Caccomo, Stephanie; Booze, Kristen; Baumgartner, Kristofer (Kristofer.Baumgartner@fda.hhs.gov); Shreeve, Chris; Hunt, Alison; Tantillo, Andrew; Gross, Karas; McBride, Maren; Anderson, Erika; Finnen, April; Cristinzio, Dayle; Walsh, Sandy; Caliguiri, Laura; Rebello, Heidi; Lynch, Sarah; Black, Jennifer; Meister, Karen G; Alexander, Nicholas; Sykes, LaShawn; Kimberly, Brad; Schipper, Jodi; Morin, Steve; Cooper, Mildred; Wohl, Alexander; Mair, Michael (Michael.Mair@fda.hhs.gov); Sadove, Elizabeth (Elizabeth.Sadove@fda.hhs.gov); Guevara, Bessy; Klimczak, Katherine; Van Pool, Kendall; Leggin, Brooke; ODonnell, Allison; Pines, Wayne *; Elicker, Janet; Roberts, Michelle; Luebke, Yasemin; Hodnette, Jonathan; Campbell, Christopher; Leboeuf, Andrew; Schumann, Katherine; Walinsky, Sarah; Kraus, Stefanie; Beers, Donald; Raza, Mark; Lenihan, Keagan; Abram, Anna; Shah, Anand
Cc: Sipes, Grail; Farley, John
Subject: Quick check in on comms for tmrw--HCQ EUA
When: Sunday, June 14, 2020 8:00 PM-8:15 PM (UTC-05:00) Eastern Time (US & Canada).
Where: webex

INTERNAL DELIBERATIVE

Hi all—sorry to ping on a Sunday, but still lots of moving pieces. Let's try to put CDER SMEs plus agency comms folks on a call to nail down timing for tomorrow. Will cancel meeting if not needed.

Join by phone
(b) (6) US Toll
(b) US Toll Free
Access code: (b) (6)

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/19/2020 3:26:06 PM
To: Guram, Jeet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ef73bea97e2b477b847ea302c4730ccf-Gurjeet.Gur]
Subject: FW: Comms Touch Base: HCQ

See below –

Let me know when you have a draft for you and me to review together? We should aim to send this out to physicians on Monday COB

Thanks,
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, June 19, 2020 2:29 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: Comms Touch Base: HCQ

FYSA – lets work with CDER on the front end of things so we don't run into this issue. Pls reach out directly to Patrizia on initial asks and she will help figure out the best way to put the info together.

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, June 19, 2020 12:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5)
[redacted]
Patrizia

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Thursday, June 18, 2020 6:44 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Don,

Here is the document with Dr. Cavazzoni edits and ORP's. Please let me know if you need anything further for your review.

Thanks,
Chris

From: Shreeve, Chris
Sent: Wednesday, June 17, 2020 5:08 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Don. We will get it through CDER as quickly as possible and then back to you.

Chris

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 4:42 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Chris,

I am glad to give my feedback now, but it would probably be good for me to look again if there are further revisions. I have a couple of comments with potential edits on the last page of the attached.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Hi,

Just checking. Has this gone through CDER or will it go there after Don clears? Thanks!

Chris

Chris Shreeve
Director, Office of Communications

Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Tel: 240-402-5772
chris.shreeve@fda.hhs.gov

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

No problem – looping in Don Beers as well, here is a first draft for review.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Jeet.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:07 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(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: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:57 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Adding Chris Shreeve, who can make sure this goes through CDER clearance, DAV in particular since they wrote the memo. I recommend that Don Beers also review.
Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:53 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Attaching the document as well

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

+Patrizia and Mary Beth for awareness. Jeet will be reaching out to CDER shortly to help pull it all together
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:39 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle

<Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Totally agree – we will build all this in and send a revised version shortly

---

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) [redacted]

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:29 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

All good feedback. Would like to emphasize that we do not regulate the (b) (5) [redacted]

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:26 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) [redacted]

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:21 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) (b) (5) [redacted]. I took a quick stab at rearranging a bit.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Great, thanks for the clarification. let's get feedback from this group and then we can circulate wider

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:02 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks – just to clarify this has not been reviewed by CDER yet

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Moving Steve to bcc

Dear All –

Following up from yesterday's discussion, Jeet worked with CDER on a proposed statement that provides scientific rationale for our decision.

We welcome your feedback.

Thank you

Anand

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 9:44 PM
To: Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Caliguiri, Laura; Rebello, Heidi; Caccomo, Stephanie; Felberbaum, Michael; Pines, Wayne *
Subject: Comms Touch Base: HCQ
When: Tuesday, June 16, 2020 8:15 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6)

From: Shah, Anand [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=E2172EBBD96946C08E189FD612855F51-ANAND.SHAH]
Sent: 6/19/2020 3:25:09 PM
To: Lenihan, Keagan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ee7320ee8c184d66bfd521b0105d17d2-Keagan.Leni]
Subject: RE: Comms Touch Base: HCQ

Will definitely do – and thanks for the feedback this afternoon

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Friday, June 19, 2020 2:29 PM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>
Subject: FW: Comms Touch Base: HCQ

FYSA – lets work with CDER on the front end of things so we don't run into this issue. Pls reach out directly to Patrizia on initial asks and she will help figure out the best way to put the info together.

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Friday, June 19, 2020 12:22 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5)
[redacted]
Patrizia

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Thursday, June 18, 2020 6:44 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Don,

Here is the document with Dr. Cavazzoni edits and ORP's. Please let me know if you need anything further for your review.

Thanks,
Chris

From: Shreeve, Chris
Sent: Wednesday, June 17, 2020 5:08 PM
To: Beers, Donald <Donald.Beers@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni,

Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Don. We will get it through CDER as quickly as possible and then back to you.

Chris

From: Beers, Donald <Donald.Beers@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 4:42 PM
To: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Chris,

I am glad to give my feedback now, but it would probably be good for me to look again if there are further revisions. I have a couple of comments with potential edits on the last page of the attached.

Don

From: Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:22 PM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Hi,

Just checking. Has this gone through CDER or will it go there after Don clears? Thanks!

Chris

Chris Shreeve
Director, Office of Communications

Center for Drug Evaluation and Research
U.S. Food and Drug Administration
Tel: 240-402-5772
chris.shreeve@fda.hhs.gov

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 3:20 PM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

No problem – looping in Don Beers as well, here is a first draft for review.

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:23 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thank you, Jeet.

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 11:07 AM
To: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5)
[redacted]

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:57 AM

To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>; Shreeve, Chris <Christine.Kuethe@fda.hhs.gov>
Cc: Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Adding Chris Shreeve, who can make sure this goes through CDER clearance, DAV in particular since they wrote the memo. I recommend that Don Beers also review.
Patrizia

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:53 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Attaching the document as well

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:52 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Cc: Cavazzoni, Patrizia <Patrizia.Cavazzoni@fda.hhs.gov>; Clarke, Mary Beth <Marybeth.Clarke@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

+Patrizia and Mary Beth for awareness. Jeet will be reaching out to CDER shortly to help pull it all together
Anand

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:39 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks!

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:35 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Totally agree – we will build all this in and send a revised version shortly

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:33 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) [redacted]

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:29 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

All good feedback. Would like to emphasize that we do not regulate (b) (5) [redacted]

From: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:26 AM
To: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) (b) (5) [redacted]

From: Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:21 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan

<Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Cristinzio, Dayle <Dayle.Cristinzio@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

(b) (5) (b) (5)
[redacted] I took a quick stab at rearranging a bit.

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:03 AM
To: Guram, Jeet <Jeet.Guram@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Great, thanks for the clarification. let's get feedback from this group and then we can circulate wider

---

From: Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:02 AM
To: Shah, Anand <Anand.Shah@fda.hhs.gov>; Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Thanks – just to clarify this has not been reviewed by CDER yet

--
Jeet Guram, M.D.
Senior Advisor, Office of the Commissioner
Food and Drug Administration
+1 (202) 230-0451 | jeet.guram@fda.hhs.gov

From: Shah, Anand <Anand.Shah@fda.hhs.gov>
Sent: Wednesday, June 17, 2020 10:01 AM
To: Lenihan, Keagan <Keagan.Lenihan@fda.hhs.gov>; Caliguiri, Laura <Laura.Caliguiri@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Pines, Wayne * <Wayne.Pines@fda.hhs.gov>; Guram, Jeet <Jeet.Guram@fda.hhs.gov>
Subject: RE: Comms Touch Base: HCQ

Moving Steve to bcc

Dear All –

Following up from yesterday's discussion, Jeet worked with CDER on a proposed statement that provides scientific rationale for our decision.

We welcome your feedback.

Thank you

Anand

-----Original Appointment-----
From: Hahn, Stephen <SH1@fda.hhs.gov>
Sent: Monday, June 15, 2020 9:44 PM
To: Hahn, Stephen; Lenihan, Keagan; Shah, Anand; Caliguiri, Laura; Rebello, Heidi; Caccomo, Stephanie; Felberbaum, Michael; Pines, Wayne *
Subject: Comms Touch Base: HCQ
When: Tuesday, June 16, 2020 8:15 AM-8:30 AM (UTC-05:00) Eastern Time (US & Canada).
Where: (b) (6)