
From: Buettner, Alexandria [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=F5F2AC69C52D4A5FB1E76816766D8D37-ALEXANDRIA.]
Sent: 8/23/2021 2:15:41 PM
To: Buettner, Alexandria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5f2ac69c52d4a5fb1e76816766d8d37-Alexandria.]
CC: Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
Subject: Invitation: Staff Briefing re FDA Approval of Comirnaty (Pfizer BioNTech COVID-19 Vaccine)

Good Afternoon,

As a follow-up to this morning's announcement (see below), the FDA Office of Legislation would like to invite you to a Hill-wide staff-level briefing regarding the approval of the Pfizer BioNTech COVID-19 vaccine, now marketed as Comirnaty to take place **tomorrow, August 24th, at 10am EST.** Please see below for details.

Details for Staff Briefing on Comirnaty Approval

Time: 10am EST, Tuesday, August 24, 2021

Phone: 1-888-947-9968

Passcode

From: Buettner, Alexandria
Sent: Monday, August 23, 2021 9:44 AM
To: Buettner, Alexandria <Alexandria.Buettner@fda.hhs.gov>
Cc: Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: FDA Approves First COVID-19 Vaccine

Good Morning,

The FDA Office of Legislation would like to bring to your attention today's announcement regarding the Pfizer BioNTech COVID-19 vaccine, which is the first vaccine approved for the prevention of COVID-19. The vaccine will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine continues to be available under EUA for those 12-15 years of age.

Please reach out to Prakash Rath (Prakash.rath@fda.hhs.gov) or Paul Aguilar (Paul.aguilar@fda.hhs.gov) with any questions.

Thank you,

Alexandria Buettner

Alexandria Buettner
Congressional Affairs Specialist

Office of Legislation
U.S. Food and Drug Administration
Mobile:
alexandria.buettner@fda.hhs.gov



FDA Approves First COVID-19 Vaccine

Approval Signifies Key Achievement for Public Health

Today, the U.S. Food and Drug Administration approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty (koe-mir'-na-tee), for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age and for the administration of a third dose in certain immunocompromised individuals.

“The FDA’s approval of this vaccine is a milestone as we continue to battle the COVID-19 pandemic. While this and other vaccines have met the FDA’s rigorous, scientific standards for emergency use authorization, as the first FDA-approved COVID-19 vaccine, the public can be very confident that this vaccine meets the high standards for safety, effectiveness, and manufacturing quality the FDA requires of an approved product,” said Acting FDA Commissioner Janet Woodcock, M.D. **“While millions of people have already safely received COVID-19 vaccines, we recognize that for some, the FDA approval of a vaccine may now instill additional confidence to get vaccinated. Today’s milestone puts us one step closer to altering the course of this pandemic in the U.S.”**

Since Dec. 11, 2020, the Pfizer-BioNTech COVID-19 Vaccine has been available under EUA in individuals 16 years of age and older, and the authorization was expanded to include those 12 through 15 years of age on May 10, 2021. EUAs can be used by the FDA during public health emergencies to provide access to medical products that may be effective in preventing, diagnosing, or treating a disease, provided that the FDA determines that the known and potential benefits of a product, when used to prevent, diagnose, or treat the disease, outweigh the known and potential risks of the product.

FDA-approved vaccines undergo the agency’s standard process for reviewing the quality, safety and effectiveness of medical products. For all vaccines, the FDA evaluates data and information included in the manufacturer’s submission of a biologics license application (BLA). A BLA is a comprehensive document that is submitted to the agency providing very specific requirements. For Comirnaty, the BLA builds on the extensive data and information previously submitted that supported the EUA, such as preclinical and clinical data and information, as well as details of the manufacturing process, vaccine testing results to ensure vaccine quality, and inspections of the sites where the vaccine is made. The agency conducts its own analyses of the information in the BLA to make sure the vaccine is safe and effective and meets the FDA’s standards for approval.

Comirnaty contains messenger RNA (mRNA), a kind of genetic material. The mRNA is used by the body to make a mimic of one of the proteins in the virus that causes COVID-19. The result of a person receiving this vaccine is that their immune system will ultimately react defensively to the virus that causes COVID-19. The mRNA in Comirnaty is only present in the body for a short time and is not incorporated into - nor does it alter - an individual’s genetic material. Comirnaty has the same formulation as the EUA vaccine and is administered as a series of two doses, three weeks apart.

“Our scientific and medical experts conducted an incredibly thorough and thoughtful evaluation of this vaccine. We evaluated scientific data and information included in hundreds of thousands of pages, conducted our own analyses of Comirnaty’s safety and effectiveness, and performed a detailed assessment of the manufacturing processes, including inspections of the manufacturing facilities,” said Peter Marks, M.D., Ph.D., director of FDA’s Center for Biologics Evaluation and Research. **“We have not lost sight that the COVID-19 public health crisis continues in the U.S. and that the public is counting on safe and effective vaccines. The public and medical community can be confident that although we approved this vaccine expeditiously, it was fully in keeping with our existing high standards for vaccines in the U.S.”**

FDA Evaluation of Safety and Effectiveness Data for Approval for 16 Years of Age and Older

The first [EUA](#), issued Dec. 11, for the Pfizer-BioNTech COVID-19 Vaccine for individuals 16 years of age and older was [based on safety and effectiveness data](#) from a randomized, controlled, blinded ongoing clinical trial of thousands of individuals.

To support the FDA's approval decision today, the FDA reviewed updated data from the clinical trial which supported the EUA and included a longer duration of follow-up in a larger clinical trial population.

Specifically, in the FDA's review for approval, the agency analyzed effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients ages 16 and older who did not have evidence of the COVID-19 virus infection within a week of receiving the second dose. The safety of Comirnaty was evaluated in approximately 22,000 people who received the vaccine and 22,000 people who received a placebo 16 years of age and older.

Based on results from the clinical trial, the vaccine was 91% effective in preventing COVID-19 disease.

More than half of the clinical trial participants were followed for safety outcomes for at least four months after the second dose. Overall, approximately 12,000 recipients have been followed for at least 6 months.

The most commonly reported side effects by those clinical trial participants who received Comirnaty were pain, redness and swelling at the injection site, fatigue, headache, muscle or joint pain, chills, and fever. The vaccine is effective in preventing COVID-19 and potentially serious outcomes including hospitalization and death.

Additionally, the FDA conducted a rigorous evaluation of the post-authorization safety surveillance data pertaining to myocarditis and pericarditis following administration of the Pfizer-BioNTech COVID-19 Vaccine and has determined that the data demonstrate increased risks, particularly within the seven days following the second dose. The observed risk is higher among males under 40 years of age compared to females and older males. The observed risk is highest in males 12 through 17 years of age. Available data from short-term follow-up suggest that most individuals have had resolution of symptoms. However, some individuals required intensive care support. Information is not yet available about potential long-term health outcomes. The Comirnaty Prescribing Information includes a warning about these risks.

Ongoing Safety Monitoring

The FDA and Centers for Disease Control and Prevention have monitoring systems in place to ensure that any safety concerns continue to be identified and evaluated in a timely manner. In addition, the FDA is requiring the company to conduct postmarketing studies to further assess the risks of myocarditis and pericarditis following vaccination with Comirnaty. These studies will include an evaluation of long-term outcomes among individuals who develop myocarditis following vaccination with Comirnaty. In addition, although not FDA requirements, the company has committed to additional post-marketing safety studies, including conducting a pregnancy registry study to evaluate pregnancy and infant outcomes after receipt of Comirnaty during pregnancy.

The FDA granted this application Priority Review. The approval was granted to BioNTech Manufacturing GmbH.

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/23/2021 8:58:38 AM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]]
CC: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]
Subject: RE: Are you OK with me flagging the Pfizer BLA PR?
Attachments: RE: Pfizer-BioNTech COVID-19 Vaccine EUA package

Dear Erica, Julie, and Lorrie,

Pfizer just confirmed receipt – its official!!!!!!

Best Regards,
Peter

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:57 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Are you OK with me flagging the Pfizer BLA PR?

Terrific, thanks much!

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:56 AM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Are you OK with me flagging the Pfizer BLA PR?

Dear Erica,

The materials were sent to the company, so please do – I suspect that they will confirm receipt while we are on the 9 AM.

Thank you so much.

Best Regards,
Peter

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:47 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Are you OK with me flagging the Pfizer BLA PR?

I'll keep it high level to let you say more, but I think it's disingenuous not to flag with the other significant media news coming out of FDA today. 😊

Congratulations Peter!
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: Tantillo, Andrew [/O=EXCHANGELABS/O U=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]
Sent: 8/23/2021 10:12:13 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

OCC on it.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 9:34 AM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Denise Zavagno

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 9:33 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Yes – Denise Hinton?

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 9:31 AM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Can you have OCC start looking at this? I know Peter is incredibly anxious to respond today. Maybe you can ask Denise to review since she haven't been working around the clock on the BLA/EUA?

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:23 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

That assumes OC and Dr. Woodcock don't have changes they would like to see. If she/you do, we would incorporate those ahead of moving it to OCC.

From: Tantillo, Andrew
Sent: Sunday, August 22, 2021 10:21 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Yes I think after any language is added from others (or even if new language is not added), we need OCC to review. We'll make sure they understand the timeline.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:19 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks! Does OCC or OGC need to review?

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:18 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

I circulated the draft for review to ASL, CDC, and NIH at 4:30, letting them know we'd like to issue tomorrow. I will follow up again in the AM

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:28 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

One of us will loop back ASAP. (For what it's worth)

(b)(5)

(b)(5)

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From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 8:53:22 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Moving Janet and Peter to bcc to spare your inbox and will loop back once it moves along. What else needs to happen for this to go out tomorrow?

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 6:33 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andi,

Thanks so much. There is some intentional repetition, as we provided a half page or so of summary at the beginning regarding the key findings from VAERS and then go into the details of how we came to those conclusions.

Thanks so much again for taking the time on a Sunday evening.

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 6:28 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter

<Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

I'm reviewing on my phone now but will note that some information appears to be repeated. In general, however, agree with this approach as well as the urgency.

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From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:26:07 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) .jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:09 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that's a great addition – a sentence like (b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:02 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

.jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

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From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Laughner, Erik [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=B77DE0AE5F3545D1BCA6ED0DB8702A2D-LAUGHNER]
Sent: 8/23/2021 12:55:08 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Approval of Comirnaty and SWG update post 08/12 meeting

OK thanks for the information and hope you are well.

Erik

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 11:01 AM
To: Laughner, Erik <Erik.Laughner@fda.hhs.gov>
Subject: RE: Approval of Comirnaty and SWG update post 08/12 meeting

Hi Erik – (b)(5)
(b)(5) I'm actually not an intended recipient here). I'd suggest adding Sarah Walinsky in my place if you haven't already. Hope you are doing well.

Thanks,

Julie

From: Laughner, Erik <Erik.Laughner@fda.hhs.gov>
Sent: Monday, August 23, 2021 10:55 AM
To: CBER FDAAA SWG <CBERFDAAAASWG@fda.hhs.gov>
Cc: Nair, Narayan <Narayan.Nair@fda.hhs.gov>
Subject: Approval of Comirnaty and SWG update post 08/12 meeting
Importance: High

Good Morning,

I wanted to provide an update to the CBER SWG with respect to this morning's important approval action of BLA 125742/0 for BNT162b2 (Comirnaty), the COVID-19 vaccine. Recall that at the 08/12 SWG meeting it was discussed that the following safety-related PMRs/PMCs were proposed:

1. A Title IX PMR to assess known serious risks of myocarditis and pericarditis and an unexpected serious risk for subclinical myocarditis; data sources are from:
 - Epidemiologic studies using large electronic healthcare databases to evaluate the occurrence of myocarditis and pericarditis in persons 16 years of age and older
US – Sentinel system (C4591009)
EU – active surveillance study (C4591021 and C4591021 sub-study)
 - Registry for long-term follow-up (in collaboration with Pediatric Heart Network)

- Prospective study to assess the incidence of subclinical myocarditis following vaccination
2. A 506B PMC for a Pregnancy registry (C4591022)
 3. A 506B PMC for a Randomized controlled trial in pregnant women (C4591015)
 4. A 506B PMC for an Active safety surveillance study among persons in the Veteran’s Affairs Health System (C4591012)

Since the SWG meeting, there was rapid discussion between OVR, OBE, Dr. Marks, and updates are provided below. While details of the specific studies for the safety PMRs were not worked out at time of SWG, this morning’s approval has 6 PMR studies to address the issues of myocarditis, pericarditis and subclinical myocarditis). In addition, there are now 2 additional clinical PMCs – one for dose ranging immunogenicity and safety study in individuals 12 through <30 years of age and an effectiveness study in Kaiser Permanente Southern CA.

Note: Title IX PMRs starts at #4 as the first 3 PMRs in the approval letter are in regard to PREA.

Study title	Discussed at 8/12 SWG (Yes/No)	Updates since 8/12 SWG if applicable	Lead reviewer
PMR#4 in approval letter: Study C4591009, entitled “A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.	Yes	N/A	OBE
PMR#5 in approval letter:: Study C4591021, entitled “Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine,” to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY.	Yes	N/A	OBE
PMR#6 in approval letter: Study C4591021 substudy to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY.	Yes	N/A	OBE
PMR#7 in approval letter: A prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination (in collaboration with Pediatric Heart Network).	Yes	N/A	OBE
PMR#8 in approval letter: A prospective assessment of the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age enrolled in Study C4591007.	The need for PMR to assess subclinical myocarditis was discussed during 8/12 SWG. Specific study design(s) was pending further sponsor negotiation. Since then,	OVR explanatory note (KF): “This [C4591007] is the same study as PMR#2 (PREA). We are requiring an evaluation of subclinical myocarditis which Pfizer will be adding through a protocol amendment to this	OVR

Study title	Discussed at 8/12 SWG (Yes/No)	Updates since 8/12 SWG if applicable	Lead reviewer
PMR#9 in approval letter: Study C4591031 substudy to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age.	OVRR has had further communication with Pfizer. OBE defers to OVRR on clinical trial Title IX PMRs.	study. Thus, we are including this study as a safety PMR for the evaluation of subclinical myocarditis. The dates for Study Completion and Final Report Submission for the subclinical myocarditis evaluation differ from those for PMR #2.”	OVRR
PMC#10 in approval letter: Study C4591022, entitled “Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post- Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry.”	Yes	N/A	OBE
PMC#11 in approval letter: An evaluation of the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through <30 years of age enrolled in Study C4591007.	No	This is an immunogenicity/effectiveness trial. OBE defers to OVRR.	OVRR
PMC#12 in approval letter: Study C4591012, entitled “Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran’s Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine.”	Yes	N/A	OBE
PMC#13 in approval letter: Study C4591014, entitled “Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California.”	No	This is a vaccine effectiveness study. OBE concurs with OVRR on listing it as a PMC.	OBE
<p>(b)(4), (b)(5)</p>			OVRR

I plan to update the 08/12 draft SWG minutes with an attached addendum to document what made into the final approval letter so we have a record.

Congrats to the review teams!

Thanks,

Erik

Erik S. Laughner, M.S., RAC | Project Management | Business Operations Staff

Strengths: Input, Discipline, Significance, Analytical, Intellection

Office of the Center Director

Center for Biologics Evaluation and Research (CBER)



10903 New Hampshire Avenue, WO71, Room 7223 | Silver Spring, MD 20993

☎ 301.796.1393 (phone)

✉ Erik.Laughner@fda.hhs.gov

Learn more about Review Management responsibilities

and Who's The Lead on topics in Review Management

<http://sharepoint.fda.gov/orgs/CBER-MRP/SitePages/Home.aspx>

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consider the environment before printing this e-mail

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Monday, August 23, 2021 9:17 AM

To: CBER Subscribers <Subscribers@fda.hhs.gov>

Subject: Approval of Comirnaty

Dear Colleagues,

Today, FDA licensed COMIRNATY (COVID-19 Vaccine, mRNA), for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. The COVID-19 vaccine continues to be available under EUA for individuals ages 12 through 15 and for a third dose for certain immunocompromised individuals.

The licensing action marks the first approval in the United States for a vaccine to prevent COVID-19 and is perhaps the Center's most significant regulatory action in decades.

Having an FDA-approved COVID-19 vaccine available may encourage more people to get vaccinated and mitigate the current rise in COVID-19 cases and hospitalizations across the US during this fourth wave of the pandemic.

This action represents a tremendous sustained effort from the Office of Vaccines Research and Review, the Office of Compliance and Biologics Quality, the Office of Biostatistics and Epidemiology and the many other teams across CBER. The quality of the work by all of the teams involved in conducting this review as thoroughly and expeditiously as possible without sacrificing our scientific standards, and under intense public pressure and scrutiny, speaks to your incredible expertise and commitment to public health.

I am incredibly proud of and humbled by the effort of all those that contributed to this major public health achievement.

My sincere congratulations to all.
Peter

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/23/2021 1:57:14 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: you ok with this?

Dear Julie,

I am fine with this language.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 1:44 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: you ok with this?

(b)(5)

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(240) 907-9331 (cell)
Julia.Tierney@fda.hhs.gov



From: Wasserman, Jill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A757986D59F4210A83E2DE2B6DD23A8-JILL.WASSER]
Sent: 8/23/2021 5:49:43 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
CC: Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: PLEASE SEE: Vax page update needed ASAP

No problem. I'll pass it along right now to CBER Web, and will let you know when it's complete. - Jill

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:48 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Jill – thanks for the information. This will be OK. But I'm sorry to say, I have another edit – it has been cleared with Peter Marks for CBER and Don Beers for OCC. This also urgently needs to be updated and should not be edited further. I've mentioned the latter point to Peter.

Thanks,
Julie

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:45 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Julie,

See attached.

Hi Julie -

From Lorrie: *Here's the track changes version. You'll see Peter's edit where he deleted the language with a question mark. We also deleted the last sentence where there was a comment asking if it was needed and CBER agreed and removed. And in the interest of complete transparency, I changed COMIRNATY to Comrinaty in the response because that's how we referred to it in the rest of the document.*

Please let me know and we'll take care of it.

Jill

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:36 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Sorry, to be clear. This has been modified slightly from what I sent and I need it to be changed to track exactly what I sent.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:30:54 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Thanks very much. I need it to have the exact verbiage I sent.

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:28:52 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

The FAQ page has been updated. [Q&A for Comirnaty \(COVID-19 Vaccine mRNA\) | FDA](#).

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:58 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Can you let me know once updated please

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:06:40 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

That's what I needed to know. Thank you.

I will send to the CBER Web team now.

Jill

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:05 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Cleared by Peter Marks for CBER, Mark Raza/Don Beers for OCC. Per Peter Marks this does not require OVRP clearance - he has cleared for the center. It is time sensitive to get these posted. Thanks for your help.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:58 PM
To: Wasserman, Jill; Tierney, Julia
Cc: Rebello, Heidi
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Thanks, Jill. Adding Julie who managed changes to this Q&A and requested the page update.

Erica

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:58 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi.

Two items of clarification:

1. Do you know who I can talk to about who cleared these changes? I ask b/c the QAs posted today had to clear CBER (OVRP & IOD), OEA and OCC and it is my understanding, we'll need to clear these too.
2. I see track changes and it looks like Julie added a question and very slightly changed one. If that's the case, we can work on clearing the one new QA and the minor modification.

I am happy to help, but want to understand what I need to do.

Thanks,

Jill

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:45 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Braithwaite, Sonia <Sonia.Braithwaite@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Ah! Thanks Jill.

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 12:43 PM
To: Jefferson, Erica; Mulieri, Chris; Braithwaite, Sonia
Cc: Rebello, Heidi
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Erica –

I believe this is a CBER web action. Let me connect with them to get the updates made ASAP.

I'll report back.

Jill

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:34 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Braithwaite, Sonia <Sonia.Braithwaite@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Subject: PLEASE SEE: Vax page update needed ASAP
Importance: High

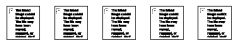
Hi Chris and Sonia –

Please see the attached below. Julie is requesting we update the website with the attached Q&A content as soon as possible. Given some of the emerging vaccine mandates, we need to ensure that the content on the page is the latest and great. Sorry it's not in tracked changes, but this was updated quickly.

Once the team is able to update, can you please confirm?

Thank you!
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov



Executive Assistant: Jacqueline.Thomas@fda.hhs.gov

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:30 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: updated QA.docx

Thanks for taking care of handling and getting updated ASAP. Please let me know once it's up and if you have any questions.

THANK YOU!!

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b)(6) (cell)
Julia.Tierney@fda.hhs.gov



From: Socgfack, Stephanie N. [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=CEABEB18DECA4A559F0A9BC76D27DFC9-STEPHANIE.S]
Sent: 8/23/2021 6:35:24 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thank you, Julie. I'm standing by.

Stephanie

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:34:28 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Just wanted to confirm that appropriate folks have touched base and are moving this forward to go our tonight.

From: Tierney, Julia
Sent: Monday, August 23, 2021 6:00:27 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Great. OL, let's take it from here and get to OES for autopen and transmittal.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Thanks so much!

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Monday, August 23, 2021 5:59 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Very clear letter. Thanks very much Peter and CBER! Jakea or Frank, this can be signed. jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Monday, August 23, 2021 5:44 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Please see the attached clean copy for your review. I removed three paragraphs toward the end that were no longer relevant. Thanks.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Monday, August 23, 2021 5:24 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Look I'll await CBER's comments since I did not author this. Happy to look at quickly then. jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Monday, August 23, 2021 5:17 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits look reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Monday, August 23, 2021 3:26 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Monday, August 23, 2021 3:25 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:26 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:09 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could (b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like: (b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

Get [Outlook for iOS](#)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Olivarria, Frank [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C180721DB774423F99990DD86E67057C-FRANK.OLIVA]
Sent: 8/23/2021 6:45:31 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Copy – I see your and Andy’s clarifying emails now, and Stephanie (OES) is looped in, so we’re rolling. We’ll let OL finish this off.

Thanks!
Frank

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:14 PM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please check w OL on this because I think this needs to get logged in their system etc

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:12:10 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

On it. Julie – would you mind forwarding the attachment that JW cleared please?

Any timing issues/request with response from the Commissioner account? If you’d like, I can check this with the OL folks.

Thank you,
Frank

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:00 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Great. OL, let’s take it from here and get to OES for autopen and transmittal.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Thanks so much!

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Very clear letter. Thanks very much Peter and CBER! Jakea or Frank, this can be signed. jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:44 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Please see the attached clean copy for your review. I removed three paragraphs toward the end that were no longer relevant. Thanks.

Best Regards,
Peter

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Sent: Monday, August 23, 2021 5:24 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Look I'll await CBER's comments since I did not author this. Happy to look at quickly then. jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:17 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits looks reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:25 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:09 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi

<Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like:

(b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:02 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 3:51 PM

To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>

Sent: Sunday, August 22, 2021 2:19 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

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From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

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Best Regards,
Peter

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To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

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believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Alexander, Uchenna [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=FA1BDD67E5534D77B04E8C8F7B658D75-UCHENNA.ALE]
Sent: 8/23/2021 7:02:06 PM
To: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Socgfack, Stephanie N. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ceabeb18deca4a559f0a9bc76d27dfc9-Stephanie.S]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Finalizing now – will send to OES in a little bit.

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:44 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Uchenna, copied, here, has OES on standby and will transmit to them for processing shortly.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:34 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Just wanted to confirm that appropriate folks have touched base and are moving this forward to go our tonight.

From: Tierney, Julia
Sent: Monday, August 23, 2021 6:00:27 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank

<Frank.Olivarria@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>

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Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Thanks so much!

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Peter

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Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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Sent: Monday, August 23, 2021 5:44 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:17 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits looks reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:25 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:09 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could (b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like: (b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:02 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 3:51 PM

To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

Get [Outlook for iOS](#)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Wasserman, Jill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A757986D59F4210A83E2DE2B6DD23A8-JILL.WASSER]
Sent: 8/23/2021 8:14:34 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: PLEASE SEE: Vax page update needed ASAP

You're welcome. -J

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:03 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Thank you so much! Appreciate your help with this today 😊

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 7:06 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Julie -

Updates are made.

Enjoy your evening,

Jill

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:48 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Jill – thanks for the information. This will be OK. But I'm sorry to say, I have another edit – it has been cleared with Peter Marks for CBER and Don Beers for OCC. This also urgently needs to be updated and should not be edited further. I've mentioned the latter point to Peter.

Thanks,
Julie

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:45 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Julie,

See attached.

Hi Julie -

From Lorrie: *Here's the track changes version. You'll see Peter's edit where he deleted the language with a question mark. We also deleted the last sentence where there was a comment asking if it was needed and CBER agreed and removed. And in the interest of complete transparency, I changed COMIRNATY to Comirnaty in the response because that's how we referred to it in the rest of the document.*

Please let me know and we'll take care of it.

Jill

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:36 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Sorry, to be clear. This has been modified slightly from what I sent and I need it to be changed to track exactly what I sent.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:30:54 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Thanks very much. I need it to have the exact verbiage I sent.

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 4:28:52 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

The FAQ page has been updated. [Q&A for Comirnaty \(COVID-19 Vaccine mRNA\) | FDA](#).

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:58 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Can you let me know once updated please

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:06:40 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

That's what I needed to know. Thank you.

I will send to the CBER Web team now.

Jill

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:05 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Cleared by Peter Marks for CBER, Mark Raza/Don Beers for OCC. Per Peter Marks this does not require OVRRClearance - he has cleared for the center. It is time sensitive to get these posted. Thanks for your help.

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:58 PM
To: Wasserman, Jill; Tierney, Julia
Cc: Rebello, Heidi
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Thanks, Jill. Adding Julie who managed changes to this Q&A and requested the page update.

Erica

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:58 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi.

Two items of clarification:

1. Do you know who I can talk to about who cleared these changes? I ask b/c the QAs posted today had to clear CBER (OVRRClearance & IOD), OEA and OCC and it is my understanding, we'll need to clear these too.
2. I see track changes and it looks like Julie added a question and very slightly changed one. If that's the case, we can work on clearing the one new QA and the minor modification.

I am happy to help, but want to understand what I need to do.

Thanks,

Jill

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:45 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>; Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Braithwaite, Sonia <Sonia.Braithwaite@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: Re: PLEASE SEE: Vax page update needed ASAP

Ah! Thanks Jill.

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Sent: Monday, August 23, 2021 12:43 PM
To: Jefferson, Erica; Mulieri, Chris; Braithwaite, Sonia
Cc: Rebello, Heidi
Subject: RE: PLEASE SEE: Vax page update needed ASAP

Hi Erica –

I believe this is a CBER web action. Let me connect with them to get the updates made ASAP.

I'll report back.

Jill

From: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:34 PM
To: Mulieri, Chris <Charles.Mulieri@fda.hhs.gov>; Braithwaite, Sonia <Sonia.Braithwaite@fda.hhs.gov>
Cc: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Subject: PLEASE SEE: Vax page update needed ASAP
Importance: High


Hi Chris and Sonia –

Please see the attached below. Julie is requesting we update the website with the attached Q&A content as soon as possible. Given some of the emerging vaccine mandates, we need to ensure that the content on the page is the latest and great. Sorry it's not in tracked changes, but this was updated quickly.

Once the team is able to update, can you please confirm?

Thank you!
Erica

Erica V. Jefferson (she/her)
Associate Commissioner for External Affairs
U.S. Food and Drug Administration
Tel: 240-702-3994
erica.jefferson@fda.hhs.gov

 The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.



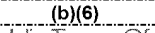
Executive Assistant: Jacqueline.Thomas@fda.hhs.gov


From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 2:30 PM
To: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: updated QA.docx

Thanks for taking care of handling and getting updated ASAP. Please let me know once it's up and if you have any questions.

THANK YOU!!

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
 (cell)
Julia.Tierney@fda.hhs.gov

 The linked image cannot be displayed. The file may have been moved, renamed, or deleted. Verify that the link points to the correct file and location.

From: Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]
Sent: 8/23/2021 10:19:21 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Letter has been transmitted!

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 6:34 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Just wanted to confirm that appropriate folks have touched base and are moving this forward to go our tonight.

From: Tierney, Julia
Sent: Monday, August 23, 2021 6:00:27 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Great. OL, let's take it from here and get to OES for autopen and transmittal.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Thanks so much!

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Very clear letter. Thanks very much Peter and CBER! Jakea or Frank, this can be signed. jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:44 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Please see the attached clean copy for your review. I removed three paragraphs toward the end that were no longer relevant. Thanks.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:24 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Look I'll await CBER's comments since I did not author this. Happy to look at quickly then. jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:17 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits looks reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia

<Julia.Tierney@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Monday, August 23, 2021 3:25 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:26 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:09 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could (b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like (b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

Get [Outlook for iOS](#)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/18/2021 6:54:21 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: FW: Your Question to Doran
Attachments: _BLA 125742 Pfizer BioNTech covid clin rev template.docx

Dear Janet,

Attached is the review memo as it stood yesterday evening. I am not fully optimistic that we will make it, particularly because the supervisors seem to be treating this like a conventional review/learning exercise, rather than an all hands on deck, work together to get it done.

I am going to provide context this AM that in the setting of this public health emergency adhering to our usual standards for safety and effectiveness means just that – it does not mean that we are bound by our usual process. If you are in agreement, I will direct the supervisors to work with the review staff collaboratively to bring these memos toward finalization. I will also tell the team that we are just going to continue working on this every day until it is done.

Looking forward to speaking at 11 AM.

Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 8:55 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Your Question to Doran

Dear Peter,

Doran has shared the email string below with me. I am attaching, for your review, the current draft of the clinical review memo. You will see that this memo still needs a lot of work and that Doran's summary of sections that will still need to be populated, revised and reviewed is an accurate and comprehensive account of the work that is still outstanding. Please also note that OVR has not received OBE's B/R summary document and the information and the assessment included in that document will also need to be captured in the clinical review memo. In addition, as mentioned by Doran in his summary the B/R table that is part of the clinical review memo still needs significant revisions and updates as per his extensive feedback to the team, which was provided to them separate from this document.

I am concerned and disappointed about the apparent lack of confidence and trust that Dr. Woodcock has in the OVR team and that she has asked you to verify the information that we have provided to you in today's meeting and in the email sent to you by Doran this afternoon. However, I understand that you do not have a choice as she directed you to personally assess and verify the work on the clinical memo that has been done so far.

I trust that, following your assessment of the attached draft clinical memo, you will come to the same conclusion about work that still needs to be completed as stated in Doran's email below and thus, an ADD of August 20 is not possible. Therefore, feel free to borrow from that summary in your response to Dr. Woodcock.

Please do not hesitate to call me this evening if you want to discuss further. As Doran's supervisor, I feel strongly that I need to provide him with some downtime at least this evening. I am confident that under Doran's guidance and leadership, the clinical team will conclude its work on this memo as soon as possible. They fully understand that the Acting Commissioner would like to approve this product very soon and are trying their best to complete their review and assessment while at the same time, maintaining our high standards and scientific and clinical integrity. Another

document that is at a very early draft stage is the SBRA and that has not even been shared with me. We have assigned this to Kirk Prutzmann who is not part of the team but capable of doing this work. We are doing what we can to accelerate the approval of this BLA.

Thank you for your understanding,
Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Tuesday, August 17, 2021 6:32 PM

To: Fink, Doran <Doran.Fink@fda.hhs.gov>

Subject: RE: Question

Dear Doran,

Dr. Woodcock has directed me to personally review and assess what we have so far before I go back to her tomorrow for a conversation about moving the action date later. Could you please point me to the Sharepoint or other site where these documents are? Thanks very much.

You are doing an amazing job and I very much appreciate the sacrifices that you have made to get this and everything else done.

Best Regards,
Peter

From: Fink, Doran <Doran.Fink@fda.hhs.gov>

Sent: Tuesday, August 17, 2021 3:52 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: Question

Hi Peter,

Over the weekend I reviewed and provided feedback on the following clinical memo sections:

- 2- Clinical and regulatory background
- 3 – Submission quality and good clinical practices
- 4 – Significant efficacy/safety issues related to other review disciplines (still need to add summary of benefit/risk analyses from Rich Forshee’s group, which they are working providing)
- 5 – Sources of clinical data and other information considered in the review
- 6 – Discussion of individual studies (The part that was ready for my review included study design, statistical considerations, demographics and disposition, and efficacy analyses; subsections on safety analyses and study conclusions were still in process)
- 11 – benefit/risk considerations table (there is more to this section, but the table is a key component that provides the framework for the benefit/risk discussion)

This week the clinical team has been working on finishing the remaining sections and responding to my feedback so far. I looked in on the memo, and many of my comments are satisfactorily addressed, but more work needed on some.

Sections that are well on their way in drafting but remaining to be completed include:

- 1 – Executive summary
- 6 – Discussion of individual studies (safety analyses and study conclusions, as mentioned above)
- 9 – Additional clinical considerations not covered elsewhere (e.g., specific populations, PREA)
- 10 – Overall conclusions

11 – Benefit/risk considerations and recommendations (in addition to the table completed this weekend)

*for anyone following along at home, sections 7 (integrated summary of efficacy) and 8 (integrated summary of safety) are not applicable for this memo.

In particular, the benefit/risk considerations are complex, and the team is doing their best to complete it along with the rest of the sections, and respond to my feedback, and resolve remaining labeling issues. They are hopeful to have a complete document for my further review by the end of this week (which I would consider a minor miracle based on how the document looks to me now), though I will continue to check in on it and check in with the team daily (or rather throughout each day) as parts are completed and as they respond to my feedback.

In addition to finishing drafting and incorporating feedback from myself, Marion, and Phil, the document will need substantial clean-up from the medical editors, which we are very happy to have at our disposal.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review

(b)(6)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Tuesday, August 17, 2021 3:25 PM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>
Subject: Question

Dear Doran,

As I go to speak to Dr. Woodcock, it would be helpful to know where you are with the clinical review, as I know that she will ask that (that is what got you invited to the last meeting with her). According to the last update that I wrote down, my understanding was that you have been reviewing the sections as they were ready and that the safety section was pending yesterday. Can you let me know where you are right now, and when you anticipate being done? Thanks so much.

And my apologies, I was wrong to be short about CDC. They are trying their hardest – I will make sure that they are properly informed on the status of things.

Best Regards,
Peter

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/19/2021 8:57:19 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: would it be possible for me to get the latest copy of the package insert?
Attachments: STN 125742.0.49_Revised PI_CBER Edits.docx

Hi Julie,

Attached is the copy of the PI draft from OVR's SP site.

Thanks,

Sana

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, August 19, 2021 8:41 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: would it be possible for me to get the latest copy of the package insert?

Dear Julie,

Happy to get this for you. Will ask the RPM for the latest version, since there were constant changes over the past day.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Thursday, August 19, 2021 8:38 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: would it be possible for me to get the latest copy of the package insert?

I know it's not finalized but would be helpful for me to see where it stands?

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602, (office) (forwarded)
(b)(6) (cell)
Julia.Tierney@fda.hhs.gov



From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/19/2021 9:27:31 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]
Subject: FW: PI
Attachments: STN 125742.0.58_ Revised PI_CBER Edits_08.18.2021.docx

Dear Julie,

This is starting to look like a real product. Please let me know if you have any questions.

Best Regards,
Peter

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Thursday, August 19, 2021 9:03 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: PI

Dear Dr. Marks,

Please see the attached with 3 comments, sent to Pfizer yesterday. It's almost there, hoping to finalize today if Pfizer agrees to our edits.

Regards,
Ram

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Thursday, August 19, 2021 8:43 AM
To: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Subject: PI

Dear Ram,

Could you send me a Word document of the latest package insert in progress – it's fine with all of the edits? Thanks so much.

Best Regards,
Peter

From: Malarkey, Mary [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=50BEADA48DCE423393136659EF12DEC2-MALARKEY]
Sent: 8/20/2021 8:29:34 AM
To: Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Finn, Theresa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7dd823be93eb40699e01c5a370b871cc-finn]
Subject: RE: follow-up on Fact Sheet and VIS

Yes . It works for me too. Thank you!

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:29 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Finn, Theresa <Theresa.Finn@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

That works for me.
Marion

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:26 AM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Sorry, I am adding Mark again.

From: Edmonds, Amanda
Sent: Friday, August 20, 2021 8:21 AM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Ok. [redacted] (b)(5)

[redacted] (b)(5)

(b)(5)

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:04 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda

I do think that would be helpful. I understand (b)(5)

(b)(4),(b)(5)

I hope that the Operation now realizes that we are going to have approved product and that they are moving towards a solution. (b)(4),(b)(5)

Thanks

Mary

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 7:53 AM

To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Sent: Friday, August 20, 2021 7:39 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

All,

(b)(4), (b)(5)

Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 4:51 AM

To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: FW: follow-up on Fact Sheet and VIS

Dear Marion and Mary,

This is OCC's opinion on using a combined Fact Sheet/VIS for the period that there is both EUA and BLA product being used. We are going to have to settle on something that can work practically from an operational perspective for the next month or two.

The Operation told us last evening that they had [redacted] (b)(4) [redacted] We can discuss this further this morning.

Julie – can you please correct me if I have gotten anything above wrong? Thanks.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Thursday, August 19, 2021 10:55 PM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: Re: follow-up on Fact Sheet and VIS

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Thursday, August 19, 2021 10:31:06 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Subject: follow-up on Fact Sheet and VIS

Hi – I connected with Amanda this evening concerning the EUA Fact Sheet and the VIS.

(b)(5)

(b)(5)

(b)(5)

From: Edmonds, Amanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=232186A24A53474298D2760C060A4CC7-AMANDA.EDMO]
Sent: 8/20/2021 8:29:28 AM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]
CC: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: follow-up on Fact Sheet and VIS

Yes

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:29 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda and Mark,

Thanks so much for this. Though I fully agree that your language for the footnote is correct, I am really concerned that the lay reader will not understand that what we are talking about here: (b)(5)
(b)(4), (b)(5) From the standpoint of what is in the vial, these products are indeed essentially interchangeable. The distinction is in regulation. That is what is important to communicate. As compromise, could you live with my redline below.

Thanks.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:21 AM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Ok. (b)(5)
(b)(5)

(b)(5)

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:04 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda

I do think that would be helpful. I understand the [redacted] (b)(5)
[redacted] (b)(4), (b)(5)

I hope that the Operation now realizes that we are going to have approved product and that they are moving towards a solution. Labeling BLA product as EUA has to end at some point.

Thanks

Mary

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 7:53 AM

To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

[redacted] (b)(5)

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Sent: Friday, August 20, 2021 7:39 AM

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Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

All,

[redacted] (b)(4), (b)(5)

Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 4:51 AM

To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

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The Operation told us last evening that they had (b)(4) (b)(4) We
(b)(4) can discuss this further this morning.

Julie – can you please correct me if I have gotten anything above wrong? Thanks.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Thursday, August 19, 2021 10:55 PM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: Re: follow-up on Fact Sheet and VIS

(b)(5)

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Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Subject: follow-up on Fact Sheet and VIS

Hi – I connected with Amanda this evening concerning the EUA Fact Sheet and the VIS. (b)(5) Happy
(b)(5) to discuss tomorrow as needed.

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/20/2021 8:44:35 AM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]
Subject: RE: follow-up on Fact Sheet and VIS

Dear Mark,

Thanks so much!

Best Regards,
Peter

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:43 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
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Thanks all. I am around today and can help out if Amanda is [REDACTED] and out of range.

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Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
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Thank you!!!

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To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
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Dear Amanda,

Thank you so much for your patience with this. We have a path forward now.

So sorry to bother you (b)(6)

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
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To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
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Dear Amanda and Mark,

Thanks so much for this. Though I fully agree that your language for the footnote is correct, I am really concerned that the lay reader will not understand that what we are talking about here (b)(5)
(b)(4),(b)(5) From the standpoint of what is in the vial, these products are indeed essentially interchangeable. The distinction is in regulation. That is what is important to communicate. As compromise, could you live with my redline below.

Thanks.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
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Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda

I do think that would be helpful. I understand the (b)(5)

(b)(4), (b)(5)

I hope that the Operation now realizes that we are going to have approved product and that they are moving towards a solution. (b)(4), (b)(5)

Thanks

Mary

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(b)(4), (b)(5)

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Julie – can you please correct me if I have gotten anything above wrong? Thanks.

Best Regards,
Peter

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Subject: follow-up on Fact Sheet and VIS

Hi – I connected with Amanda this evening concerning the EUA Fact Sheet and the VIS.

(b)(5)

(b)(5)

Happy

to discuss tomorrow as needed.

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
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To: Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: follow-up on Fact Sheet and VIS
Attachments: EUA Fact sheet for Recipients - Pfizer-BioNTECH COVID-19 Vaccine_FINAL (VIS_08.20).docx

Thanks so much again for all you help Amanda. Attached is a clean Fact Sheet with the footnote incorporated for where we use the phrase (b)(5) for you to forward to CDC.

I hope you enjoy the (b)(6)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:46 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

THanks, Mark! We hope to hit (b)(6) today 😊

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:43 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
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Subject: RE: follow-up on Fact Sheet and VIS

Ok, great. (b)(5)

(b)(5)

Just let me know.

I'll be (b)(6) today but will have my work phone (b)(6) and personal cell (b)(6) with me, and will keep an eye on work email for these issues.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:35 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
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Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

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

(b)(5)

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Dear Amanda

I do think that would be helpful. [redacted] (b)(5)
[redacted] (b)(4), (b)(5)

I hope that the Operation now realizes that we are going to have approved product and that they are moving towards a solution. [redacted] (b)(4), (b)(5)

Thanks

Mary

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(b)(4), (b)(5)

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(b)(5)

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Happy

to discuss tomorrow as needed.

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Sent: 8/20/2021 3:07:57 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: FW: follow-up on Fact Sheet and VIS

The paragraph is below.

From: Hussain, Sana
Sent: Friday, August 20, 2021 2:46 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Peter,

Below is the language that Marion and her team is proposing. It doesn't change the substance, but provides a bit more clarity. I just want to make sure you're comfortable with it. I will be making conforming changes throughout the documents (both FSs and LOA). They also had a clarification question for OCC re: (b)(5) (b)(5) (b)(5) I'll copy you on my email with Amanda.

COMIRNATY (COVID-19 Vaccine, mRNA) is an FDA-approved COVID-19 vaccine made by BioNTech. It is approved for use in individuals 16 years of age and older. COMIRNATY is also authorized for emergency use in individuals 12 through 15 years and to provide a third dose to individuals 12 years of age and older who have been determined to have certain kinds of immunocompromise. COMIRNATY has the same formulation as the Pfizer-BioNTech COVID-19 Vaccine. These vaccines can be used interchangeably to provide the COVID-19 vaccination series.^[1]

FN 1: Although the licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns, the products are legally distinct products.

Thanks,

Sana

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:47 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Dear Sana,

Probably better to send to CDC for comment first. Pfizer won't have much choice. Thanks

Best Regards,
Peter

^[1] Although the licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns, the products are legally distinct products.

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To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Peter,

I am adding the changes, but do we want to talk to Pfizer first before we send to CDC?

Thanks,

Sana

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
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To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
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Dear Mark,

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To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Thanks all. I am around today and can help out if Amanda is on a (b)(6) and out of range.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 8:41 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Ok, great. Sana, can you make the changes

(b)(5)

(b)(5)

Just let me know.

I'll be (b)(6) today but will have my work phone (b)(6) and personal cell (b)(6) with me, and will keep an eye on work email for these issues.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:35 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: Re: follow-up on Fact Sheet and VIS

Thank you!!!

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:33:27 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda,

Thank you so much for your patience with this. We have a path forward now.

So sorry to bother you (b)(6)

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:30 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:29 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>

Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda and Mark,

Thanks so much for this. Though I fully agree that your language for the footnote is correct, I am really concerned that the lay reader will not understand that what we are talking about here (b)(5)

(b)(5) From the standpoint of what is in the vial, these products are indeed essentially interchangeable. The distinction is in regulation. That is what is important to communicate. As compromise, could you live with my redline below.

Thanks.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:21 AM

To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Ok, [redacted] (b)(5)

[redacted] (b)(5)

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Sent: Friday, August 20, 2021 8:04 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda

I do think that would be helpful. I understand [redacted] (b)(5)

I hope that the Operation now realizes that we are going to have approved product and that they are moving towards a solution. [redacted] (b)(4), (b)(5)

Thanks

Mary

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 7:53 AM

To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

[redacted] (b)(5)

(b)(5)

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Sent: Friday, August 20, 2021 7:39 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

All,

(b)(4), (b)(5)

Marion

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 4:51 AM

To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: FW: follow-up on Fact Sheet and VIS

Dear Marion and Mary,

This is OCC's opinion on using a combined Fact Sheet/VIS for the period that there is both EUA and BLA product being used. We are going to have to settle on something that can work practically from an operational perspective for the next month or two.

The Operation told us last evening that they had (b)(4) (b)(4) We can discuss this further this morning.

Julie – can you please correct me if I have gotten anything above wrong? Thanks.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Thursday, August 19, 2021 10:55 PM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: Re: follow-up on Fact Sheet and VIS

(b)(4), (b)(5)

(b)(4), (b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Thursday, August 19, 2021 10:31:06 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Subject: follow-up on Fact Sheet and VIS

Hi – I connected with Amanda this evening concerning the EUA Fact Sheet and the VIS.

(b)(5)

(b)(5)

Happy

to discuss tomorrow as needed.

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/21/2021 8:55:40 AM
To: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: EUA Fact Sheet; BLA info sheet
Attachments: Fact sheet for Recipients - (EUA-BLA)_ABE (1).docx

Dear Sana,

I am really sorry about this, but I was working on the fact sheet at the same time you were. I really feel strongly that we need to be very consistent with the naming throughout and also streamline where possible. Please see the attached. I don't think it is all that far off from your version, and you can hopefully merge them without too much difficulty. After the 9 AM perhaps we can clean these up and send to OVRP – will call you.

Best Regards,
Peter

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:21 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Hi Peter and Julie,

Please see the attached revised fact sheet. I've addressed most of OCC's comments. I defer to you both on the title, but currently, it has been changed to "Fact Sheet for...". Also, do we have a preference on the alternative language at the end of the text box? I am also happy to choose if you all prefer.

Thanks so much,

Sana

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:12 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Dear Amanda,

My sincere thanks too! Hope that you have a wonderful day.

Best Regards,
Peter

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:02 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Thanks so much, Amanda!

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:00 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Please see attached for OCC's comments and edits (not too many).

From: Edmonds, Amanda
Sent: Friday, August 20, 2021 9:49 PM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Thanks, I will review this in the morning.

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Friday, August 20, 2021 9:27 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Hi Mark and Amanda,

Please see the attached "Vaccine Information Sheet," which incorporates both the BLA & EUA product. Please let us know if you have any comments and edits.

Peter copying you here. Hopefully you can take a look after OCC reviews.

Thanks,

Sana

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 6:41 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: EUA Fact Sheet; BLA info sheet

Hi – I spoke with Amanda and updated her on the latest. We are happy to review the next version you all send. Let us know if you would like to talk.

From: Edmonds, Amanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=232186A24A53474298D2760C060A4CC7-AMANDA.EDMO]
Sent: 8/21/2021 9:04:12 AM
To: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:46 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

From my understanding: (b)(5)

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:23 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

(b)(5)

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:39 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:42 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:36 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda,

We'll work through this. We will just have to find something practical to implement, given this is the worst pandemic in a the century.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 6:08 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:59 PM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Sana – I'm sorry but I am not exactly sure

(b)(5)

(b)(5)

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:38 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: FW: follow-up on Fact Sheet and VIS

Hi Mark,

We were hoping you could help us with the question we posed to Amanda below re:

(b)(5)

Any insight would be greatly appreciated.

Sana

From: Hussain, Sana
Sent: Friday, August 20, 2021 2:59 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Amanda,

I know we're still waiting on the okay from CDC, but OVRP had one question as they were reviewing the language in the FS (which they had some clarifying edits, but substantively it remains the same). They are curious re: (b)(5)

(b)(5)

(b)(5) think there was some confusion and any insight that you have would be greatly appreciated.

Sorry for the trouble (and I do hope you (b)(6) is going okay).

Sana

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:02 AM

To: Malone, Kevin M (CDC) <kmm2@cdc.gov>

Cc: Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>; Thombley, Melisa L (CDC) <fsy1@cdc.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: FW: follow-up on Fact Sheet and VIS

Kevin, as discussed, here is a combined Fact Sheet/VIS for the EUA product and the BLA product. (b)(5)

(b)(5) Please copy Mark and Sana on any reply.

Thanks,
Amanda

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:00 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Thanks so much again for all you help Amanda. Attached is a clean Fact Sheet with the footnote incorporated for where we use the phrase (b)(5) for you to forward to CDC.

I hope you enjoy the (b)(6)

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/21/2021 11:00:09 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Fact sheet for Recipients - (EUA-BLA)_ABE_PM (08.21) Clean.docx
Attachments: Fact sheet for Recipients - (EUA-BLA)_ABE_PM (08.21) Clean.docx

From: Wasserman, Jill [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=0A757986D59F4210A83E2DE2B6DD23A8-JILL.WASSER]
Sent: 8/21/2021 1:42:13 PM
To: Madni, Rubina [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d6173079ca1d4ebe9e41a770df07016e-Rubina.Madni]
CC: Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: RE: FOR OCC REVIEW: Responsive & Public-facing QAs for Comirnaty
Attachments: FDA Cleared_130pm_8-21-2021 Comirnaty QAs for reactive use.docx

+Erica

Dear Rubina and all,

Thanks for this information and your review. We decided to [REDACTED] (b)(5)

[REDACTED] (b)(5)

[REDACTED] (b)(5)

If you need OEA to clear, please let us know.

Best,

Jill

From: Madni, Rubina <Rubina.Madni@fda.hhs.gov>
Sent: Saturday, August 21, 2021 12:04 PM
To: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>
Cc: Walsh, Sandy <Sandy.Walsh@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: FOR OCC REVIEW: Responsive & Public-facing QAs for Comirnaty

Dear Jill,

[REDACTED] (b)(5)

Copying Peter, Julie, and Sana because they've been looped into the discussion re: the HHS language.

I'm reviewing the web posting QAs now and will send you my comments shortly.

Thanks,
Rubina

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>

Sent: Friday, August 20, 2021 1:55 PM

To: OC OCC Biologics Team Assignments <OCOCCBiologicsTeamAssignments@fda.hhs.gov>

Cc: Madni, Rubina <Rubina.Madni@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Osterman, Rachel <Rachel.Osterman@fda.hhs.gov>; Zavagno, Denise <Denise.Zavagno@fda.hhs.gov>; Capobianco, Abigail <Abigail.Capobianco@fda.hhs.gov>; Hunt, Alison <Alison.Hunt@fda.hhs.gov>; Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>; Frantz-Bohn, Susan <Susan.Frantzbohn@fda.hhs.gov>

Subject: FOR OCC REVIEW: Responsive & Public-facing QAs for Comirnaty

Dear OCC colleagues,

Attached are CBER-cleared QAs, both responsive and ones for web-posting for the upcoming approval of Comirnaty.

I have been told that we want everything cleared by Sunday afternoon, but I have also been asked if you could clear the responsive QAs ASAP.

Please let me know if you want to discuss or have any questions.

Thank YOU,

Jill Wasserman, MPH

Rollout Coordinator, Office of External Affairs

U.S. Food and Drug Administration

Work Cell [REDACTED] (b)(6)

Jill.Wasserman@fda.hhs.gov



From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/21/2021 2:51:21 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: EUA Fact Sheet; BLA info sheet
Attachments: Fact sheet for Recipients - (08.21).docx

Hi Julie,

Attached is the clean version of the Recipient FS.

Thanks,

Sana

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Saturday, August 21, 2021 1:54 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Dear Julie,

At about 2:15 we are going to have pens down and share the VIS/Fact sheet with Pfizer. At that point, Sana can send you a copy to share with Anita. Thanks very much!

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Saturday, August 21, 2021 12:20 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Peter and Sana,

Please let me know when you are in a spot where you would feel comfortable with me sharing this with Anita Patel at the CAG close hold for operational red flags (I will not be entertaining any wordsmithing) – and send along to me. All of this to facilitate roll out on Monday and make sure loose ends are tied. I continue to emphasize very close hold regardless of what the NYT is reporting.

Thanks,
Julie

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:57 AM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Dear Julie,

Thanks. We will probably go with something a bit longer.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:49 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Thanks so much! For the title of the document, (b)(5)
(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:21 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Hi Peter and Julie,

Please see the attached revised fact sheet. I've addressed most of OCC's comments. I defer to you both on the title, but currently, it has been changed to "Fact Sheet for...". Also, do we have a preference on the alternative language at the end of the text box? I am also happy to choose if you all prefer.

Thanks so much,

Sana

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:12 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Dear Amanda,

My sincere thanks too! Hope that you have a wonderful day.

Best Regards,
Peter

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:02 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Thanks so much, Amanda!

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:00 AM

To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Please see attached for OCC's comments and edits (not too many).

From: Edmonds, Amanda
Sent: Friday, August 20, 2021 9:49 PM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Thanks, I will review this in the morning.

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Friday, August 20, 2021 9:27 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: EUA Fact Sheet; BLA info sheet

Hi Mark and Amanda,

Please see the attached "Vaccine Information Sheet," which incorporates both the BLA & EUA product. Please let us know if you have any comments and edits.

Peter copying you here. Hopefully you can take a look after OCC reviews.

Thanks,

Sana

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 6:41 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: EUA Fact Sheet; BLA info sheet

Hi – I spoke with Amanda and updated her on the latest. We are happy to review the next version you all send. Let us know if you would like to talk.

From: Edmonds, Amanda [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=232186A24A53474298D2760C060A4CC7-AMANDA.EDMO]
Sent: 8/21/2021 3:22:51 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: Re: follow-up on Fact Sheet and VIS

Very good, thanks.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Saturday, August 21, 2021 3:00:30 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Re: follow-up on Fact Sheet and VIS

Just to circle back on this, we're working towards imposing all of the AE reporting requirements in the LOA on HCPs regardless of whether they are administering the BLA product or the EUA product and regardless of what approved or authorized use.

We'll do this two ways:

1. CDC will update the Provider Agreement to make clear that the AE reporting in the agreement (which tracks the LOA) is applicable to both EUA and BLA product. They will make corresponding changes to the VAERS website. Since the PI links to that website, we should be OK from that perspective. I've spoken with CDC lawyer and it will be taken care of.
2. Modifying the LOA to make clear EUA AE reporting conditions in the LOA apply when BLA product is used for an authorized use. Sana is leading on that.

Thanks,
Julie

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Saturday, August 21, 2021 9:06:57 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 9:03 AM

To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:46 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

From my understanding

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:45 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Yes, that section.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:37 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

I think it is, Mark. This is the section you mean, right

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:34 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Sorry – related issue

(b)(5)

(b)(5)

I think it is but am not sure.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:23 AM

To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

(b)(5)

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:39 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:42 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:36 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda,

We'll work through this. We will just have to find something practical to implement, given this is the worst pandemic in a the century.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:08 PM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Same here

(b)(5)

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:59 PM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Sana – I'm sorry but I am not exactly sure.

(b)(5)

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:38 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: FW: follow-up on Fact Sheet and VIS

Hi Mark,

We were hoping you could help us with the question we posed to Amanda below re:

(b)(5)

Any insight would be greatly appreciated.

Sana

From: Hussain, Sana
Sent: Friday, August 20, 2021 2:59 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Amanda,

I know we're still waiting on the okay from CDC, but OVRP had one question as they were reviewing the language in the FS (which they had some clarifying edits, but substantively it remains the same). They are curious re:

(b)(5)

(b)(5)

(b)(5)

I think there was some confusion and any insight that you have would be greatly appreciated.

Sorry for the trouble (and I do hope: (b)(6) is going okay).

Sana

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 9:02 AM
To: Malone, Kevin M (CDC) <kmm2@cdc.gov>

Cc: Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>; Thombley, Melisa L (CDC) <fsy1@cdc.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: FW: follow-up on Fact Sheet and VIS

Kevin, as discussed, here is a combined Fact Sheet/VIS for the EUA product and the BLA product: (b)(5)

(b)(5)

Please copy Mark and Sana on any reply.

Thanks,
Amanda

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:00 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Thanks so much again for all you help Amanda. Attached is a clean Fact Sheet with the footnote incorporated for where we use the phrase (b)(5) for you to forward to CDC.

I hope you enjoy (b)(6)

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/22/2021 10:25:33 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002).docx
Attachments: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfh.docx

I think I agree with your suggestions and included comments re: where you indicated it was yellow.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:03 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002).docx

Use this version

From: Tierney, Julia
Sent: Sunday, August 22, 2021 9:03 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002).docx

Highlighting system – red means no, we won't take; yellow, let's discuss; green, should accept. I've checked with OCC

(b)(5)

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/22/2021 12:00:35 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: HOLD: Sync up
Attachments: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjt.docx

Hi Peter,

I am email the document with CDC's edits for our discussion at 1pm (apologies as I can't seem to upload it to the meeting invite). We can walk through this together during the meeting.

Just flagging the Julie has pushed back on CDC noting that this is an FDA document.

Highlighting system –

- red means no, we won't take;
- yellow, let's discuss;
- green, should accept.

I'll circulate Pfizer's comments as soon as we receive them.

Thanks,

Sana

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

From: Hussain, Sana
Sent: Sunday, August 22, 2021 9:44 AM
To: Hussain, Sana; Marks, Peter; Tierney, Julia
Subject: HOLD: Sync up
When: Sunday, August 22, 2021 1:00 PM-1:30 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Microsoft Teams Meeting

Holding time for noon.

To discuss comments on the Fact Sheets. I hope we will have Pfizer's comments to the FS as well by this point.

Please let me know if this time does not work.

Thank you!

Microsoft Teams meeting

Join on your computer or mobile app

[Click here to join the meeting](#)

Or call in (audio only)

+1 202-964-4011, **(b)(6)** United States, Washington DC

Phone Conference ID: **(b)(6)**

[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/22/2021 1:02:06 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: DRAFT Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjct.docx
Attachments: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjct.docx

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/22/2021 1:59:46 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: CDC recipient Fact Sheet
Attachments: CLEAN_Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjt.docx; Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjt.docx

Hi Julie,

Do you want me to clean the comments up? Just let me know.

Thanks!

Sana F. Hussain, J.D.

Regulatory Counsel

Regulations and Policy Staff

Office of the Director

Center for Biologics Evaluation and Research

FDA | CBER | OD | RPS

Tel: 301.348.3994 | sana.hussain@fda.hhs.gov

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/22/2021 2:07:22 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: Pfizer FS drafts (with our edits)
Attachments: Pfizer 1135AM- Emergency Use_Full Prescribing Info_HCP Fact Sheet Pfizer-BioNTECH COVID-19 vaccine_21Aug21_sfh.docx; Pfizer 1155AM EUA Fact sheet for Recipients - Pfizer-BioNTECH COVID-19 Vaccine_21Aug21_sfh.docx

Please see the attached Pfizer ones we just went through.

Thanks!

Sana F. Hussain, J.D.
Regulatory Counsel

Regulations and Policy Staff
Office of the Director
Center for Biologics Evaluation and Research
FDA | CBER | OD | RPS
Tel: 301.348.3994 | sana.hussain@fda.hhs.gov

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 8/22/2021 4:12:12 PM
To: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

That would be great. I think that we should treat this as a somewhat urgent response, as the Senator the letter that he has disseminated widely is now spreading more vaccine misinformation.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:09 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like:

(b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia

<Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

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From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Rebello, Heidi [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=2834CE193CA949799EF063E34A2CFA0B-HEIDI.REBEL]
Sent: 8/22/2021 8:58:05 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL
Attachments: REDLINED_FDA CLEARED_Comirnaty All Hands for JW_8.22.2021_840pm (SW proof).docx

It's now consistent with final version of PR. See minor redlined version in first paragraph. Thanks!

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Sunday, August 22, 2021 6:31 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

Will double check!

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From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 5:59:45 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

I was just on the phone w Peter on something else and he commented about the PR – just checking is the first line of this the final language that CBER provided a few minutes ago?

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Sunday, August 22, 2021 5:58 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>
Subject: RE: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

Dr. Woodcock, sharing the final version of your all hands. We ensured the indication language is consistent with the final PR language [REDACTED (b)(5)] Clean copy attached. I anticipate this will go out around 9:45 a.m. tomorrow. Thank you.

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, August 21, 2021 1:41 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Re: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

Sounds good!

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From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Saturday, August 21, 2021 1:22:44 PM
To: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

I'm ok with this except [REDACTED] jw

From: Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Sent: Saturday, August 21, 2021 11:32 AM
To: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: RE: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

Dr. Woodcock, please review this version of your all hands. CBER had a few tweaks. Thank you.

<< File: BLA draft all hands JW_V2 review.docx >>

From: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Sent: Friday, August 20, 2021 5:53 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>; Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Flahive, James <James.Flahive@fda.hhs.gov>
Subject: FRIDAY HOMEWORK 08.20.21 - INTERNAL CONFIDENTIAL

Dr. Woodcock,

For your action (two items):

ITEMS FOR YOUR REVIEW

Action: Review for edits/feedback, requested by:

Monday, 8/23, 9:00 AM:

<< File: World Orphan Drug Congress - Q and As.docx >>

Action: Review for edits/feedback, requested by:

Monday, 8/23, 9:00 AM:

<< File: BLA draft all hands.docx >>

ITEM #1: Acting Commissioner Remarks: World Orphan Drug Congress

- **Event Date:** 8/26: 8:55 AM – **Prerecording:** 8/23: 2:30 PM
- **Note:** Interviewer, Dr. Ed Neilan of NORD, will ask 4-6 questions during the allotted 20 minute timeslot.
- **HW POC:** Alex Whol (OEA/OECS)

ITEM #2: Acting Commissioner All Hands: CBER BLA action

- **Event Date:** TBD
- **HW POC:** Heidi Rebello (OEA)

Thank you,

Frank

Frank A. Olivarria
Management and Program Analyst
Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Tel: [240-402-9882](tel:240-402-9882)
Frank.Olivarria@fda.hhs.gov

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 8/22/2021 11:17:42 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: UPDATE #2: Read Ahead for Mon, August 23, 2021
Attachments: 0930+1100-1-Pfizer BLA Call Script 8.22.21 FINAL 738PM.docx; 0930+1100-2-FDA CLEARED Comirnaty QAs for reactive use_8.21.2021_130pm_forDrsW&M .docx; 0930+1100-3-FDA CLEARED Comirnaty QAs for web posting_8.22.21_830pm_forDrsW&M.docx; 0930+1100-4-FDA QandA re BLA re off label 082221_930pm.docx

Dr. Woodcock,

Attached please find updated materials for reference at tomorrow's "internal media prep" and "media call".

Jakea

From: Copeland, Jakea
Sent: Sunday, August 22, 2021 9:46 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Subject: UPDATED: Read Ahead for Mon, August 23, 2021

MEETING MATERIALS:

9:30am *Internal Prep for Media Call*

11am *Media Call - same materials referenced at 9:30am prep call*

4pm *Cures Compensation Review Board*

OEA/OMA READING:

1. FDA Communications Forecast (Mon., Aug. 23 - Fri., Sep. 3)

Jakea

From: Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Sent: Saturday, August 21, 2021 9:44 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>
Subject: Read Ahead for Mon, August 23, 2021

MEETING MATERIALS:

4pm Cures Compensation Review Board

OEA/OMA READING:

1. FDA Communications Forecast (Mon., Aug. 23 - Fri., Sep. 3)

Jakea Copeland

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Desk Phone: (301) 796-7050

Email: Jakea.Copeland@fda.hhs.gov



From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/23/2021 8:32:36 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: FW: BLA Comirnaty - sign off on clinical review memo
Attachments: STN 125742-0 Approval letter_final.pdf; STN 125742-0_SBRA_Ramachandra Naik_8.23.2021_rsn.pdf; STN125742.0-Transmittal Memo.pdf

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:31 AM
To: Sadove, Elizabeth <Elizabeth.Sadove@fda.hhs.gov>; Courtney, Brooke <Brooke.Courtney@fda.hhs.gov>
Cc: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: FW: BLA Comirnaty - sign off on clinical review memo

Dear Liz and Brooke,

Please see the attached. The approval letter has been signed. Please proceed with the LoA/EUA materials.

Best Regards,
Peter

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:29 AM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Dear Ram,
All three documents have been signed off and locked.
Marion

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:20 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

OK – I went ahead per instructions. Here they are unlocked

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:10 AM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>
Cc: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

just talked to Peter, he asked to wait until 8:15 am, if clinical memo not signed by then, we start our sign off.

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:06 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Ok – I'll hang

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:05 AM
To: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Wait 10 more minutes so that we can be sure memo is signed. Peter is a bit behind too, I guess, he was supposed to call me at 8:00 am 😊

From: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:04 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Should I go ahead?

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Monday, August 23, 2021 7:57 AM
To: Fink, Doran <Doran.Fink@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Great!

From: Fink, Doran <Doran.Fink@fda.hhs.gov>
Sent: Monday, August 23, 2021 7:56 AM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>
Subject: RE: BLA Comirnaty - sign off on clinical review memo

Update – just heard that the memo is ready to PDF and sign, so they are working on that now.

Thanks,
Doran

Doran L. Fink, MD, PhD
Deputy Director – Clinical
Division of Vaccines and Related Products Applications
FDA/CBER, Office of Vaccines Research and Review
(301) 796-2640

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>

Sent: Monday, August 23, 2021 7:54 AM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>

Cc: Malarkey, Mary <Mary.Malarkey@fda.hhs.gov>; Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>; Dickerson, David <David.Dickerson@fda.hhs.gov>; Fink, Doran <Doran.Fink@fda.hhs.gov>

Subject: BLA Comirnaty - sign off on clinical review memo

Dear Peter,

The clinical review memo is final and the editors finished cleaning it up overnight. However, the clinical team is working currently through some technical issues on SharePoint, they are trying to get the memo finalized and signed within the hour. Thus, these are solely IT issues that prevent us from finalizing and signing the memo. I suggest to go forward with signing off on the approval. The clinical review memo will be signed off and uploaded once SP issues are solved.

Marion

Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856

Email: marion.gruber@fda.hhs.gov



From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 8/5/2021 6:38:33 PM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]; Gottschalk, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9839a4146ef74943b3bd34fadcd29132-Laura.Gotts]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Fink, Doran [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b3bfbf3e7bea40b1b726937796eba4e8-FinkDo]; Pratt, Douglas R. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=682a5e028a4e428aa16bc3c206518d81-pratt]; McVittie, Loris [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dad145be676748898016f37b0760bc61-mcvittie]; Wollersheim, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00541f26747c48c09d7b38f8968d3e0e-Susan.Wolle]; Lee, Lucia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c2d89bf8adec408fb3dd10c29d63d0fc-Leel]; Schwartz, Ann T [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dd85358364f54b2d9f823d3f79ab7f2e-SchwartzA]; Allende, Maria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3eb3dba5ebf44aabac32aa1a5b58d83-ALLENDEM]; Wang, Xiao [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1426adeb382244069b33af38c73358aa-WangXia]; Cheung, Anissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5a5e55be048a4eb7ae6ccf49aa9e58b3-CheungA]; Wang, Hsiaoling [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d2940f1d718047d1bc9845af576ba17e-WangH]; Yitbarek, Emnet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=be4b6baec6934430b62c24070d2502c8-Emnet.Yitba]; Garcia, Karla [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7187f0f732fb404493d20fa51cf246e1-Karla.Garci]; Choudhary, Anil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=15945f881e8849b1a1addfa50fab83f6-ChoudharyA]; Alvarado, Esmeralda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d23ee59ef3a04eaaba82cfcdd3afd5ce-Esmeralda.A]; Anderson, Marie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4b8be33bb5c6478db7f097604e4d02e3-Marie.Ander]; Hulme, Cheryl [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5d842ca821194097ba71c3719c256317-hulme]; Al-Humadi, Nabil [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9683cea1300a4f739790dc8ad4eb6fbf-AlHumadiN]; Huang, Lei [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=58ce4f4d0fc84e41b240cc839cc67bec-Lei.Huang]; Yang, Ye [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=64dd48cb8d35427c9cd0a14a1cecfb48-Ye.Yang]; Tang, Xinyu [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=81044057bca044c0b8080a865507cd08-Xinyu.Tang]; Thompson, Deborah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b1daeb32ffc4eb9ad43753eb1af30a2-Deborah.Tho]; Jones, Kathleen (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39f078595fe54c58963eccae13a653e8-Kathleen.Jo]; Fontan, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=254ab94e05104f5e89cd4ae937093214-Laura.Fonta]; Price, Gregory

[/o=ExchangeLabs/ou=Exchange Administrative Group
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Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Meeting with Dr. Marks (entire review team)

Location: Zoom [redacted] (b)(6)

Start: 8/13/2021 2:00:00 PM

End: 8/13/2021 3:00:00 PM

Show Time As: Tentative

Required Attendees: Gottschalk, Laura; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiohjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert; Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Hussey, Deirdre; McNeill, Lorrie; Richardson, Anita F (CBER)

Rescheduled because of conflicts.

This meeting with Dr. Marks is to discuss the review progress of the COMIRNATY BLA (STN 125742/0) with the entire review team, and to provide updates.

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Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

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CC: Maloney, Diane [Diane.Maloney@fda.hhs.gov]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Witten, Celia (CBER) [Celia.Witten@fda.hhs.gov]; Welsh, Kerry [Kerry.Welsh@fda.hhs.gov]; Zinderman, Craig E [Craig.Zinderman@fda.hhs.gov]; Hussey, Deirdre [Deirdre.Hussey@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Richardson, Anita F (CBER) [Anita.Richardson@fda.hhs.gov]
Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Follow-up meeting with Dr. Marks
Location: Zoom [REDACTED] (b)(6)
Start: 8/6/2021 4:00:00 PM
End: 8/6/2021 4:30:00 PM
Show Time As: Tentative

Required Attendees:

Naik, Ramachandra; Gottschalk, Laura; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiojwen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert

Optional Attendees:

Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Deirdre Hussey; McNeill, Lorrie; Richardson, Anita F (CBER)

This meeting with Dr. Marks is to discuss the review progress of the COMIRNATY BLA (STN 125742/0), and to provide updates.



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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Walinsky, Sarah
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Witten, Celia (CBER)

[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Welsh, Kerry
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39b32156b8d34975a1093048aa852589-Kerry.Welsh]; Zinderman, Craig E
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4692e9d598c744ecb344f80c34246ea5-Zinderman]; Hussey, Deirdre
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=41a51a9bf937431c8470b69fb055fe81-Husseyd]; McNeill, Lorrie
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Richardson, Anita F (CBER)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0264e1cf8edd4b1ebc2ef1eb94a28da4-RichardsonA]
Frantz-Bohn, Susan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4c4a10821c774ffa9c5cf59bda6bcf75-frantz_bohn]; Kaelber, Nadine
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7c0ffef59ba047ba8616ca092e695e19-Nadine.Kael]; Taylor, Leslie
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=80f52c2786a847458b21c4414e843249-Leslie.Tay]; Kong, Hyesuk
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ad92c718450c451aa403cf73682791d9-Kong]

CC:

Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Meeting with Dr. Marks (entire review team)

Location: Zoom [redacted (b)(6)]

Start: 8/20/2021 10:30:00 AM

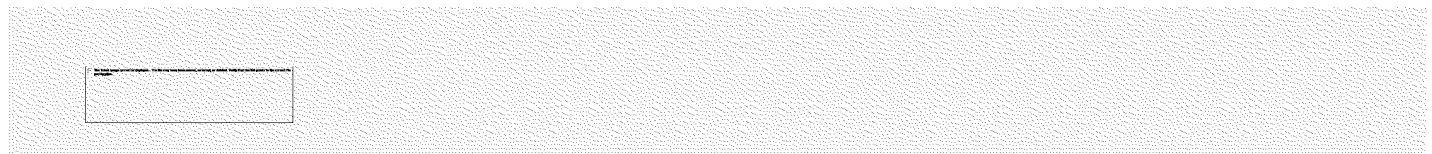
End: 8/20/2021 11:30:00 AM

Show Time As: Tentative

Required Attendees: Gottschalk, Laura; Marks, Peter; Gruber, Marion; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiojwen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert; Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Hussey, Deirdre; McNeill, Lorrie; Richardson, Anita F (CBER)

Optional Attendees: Frantz-Bohn, Susan (Susan.Frantzbohn@fda.hhs.gov); Kaelber, Nadine; Taylor, Leslie; Kong, Hyesuk

This meeting with Dr. Marks is to discuss the review progress of the COMIRNATY BLA (STN 125742/0) with the entire review team, and to provide updates.



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833 568 8864 (Toll Free)

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(b)(6)

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H.323:

Meeting

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(b)(6)

Passcode

SIP:

Passcode

From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 8/16/2021 12:14:14 PM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Forshee, Richard [Richard.Forshee@fda.hhs.gov]; Yang, Ye [Ye.Yang@fda.hhs.gov]; Nair, Narayan [Narayan.Nair@fda.hhs.gov]; Niu, Manette [Manette.Niu@fda.hhs.gov]; Alimchandani, Meghna [Meghna.Alimchandani@fda.hhs.gov]; Gruber, Marion [Marion.Gruber@fda.hhs.gov]; Krause, Philip [Philip.Krause@fda.hhs.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Finn, Theresa [Theresa.Finn@fda.hhs.gov]; Izurieta, Hector [Hector.Izurieta@fda.hhs.gov]; Roberts, Jeff [Jeff.Roberts@fda.hhs.gov]; Fink, Doran [Doran.Fink@fda.hhs.gov]; Pratt, Douglas R. [Douglas.Pratt@fda.hhs.gov]; McVittie, Loris [Loris.McVittie@fda.hhs.gov]; Prutzman, Kirk C [Kirk.Prutzman@fda.hhs.gov]; Sutkowski, Elizabeth M. [Elizabeth.Sutkowski@fda.hhs.gov]; Smith, Michael (CBER) [Michael.Smith2@fda.hhs.gov]; Gottschalk, Laura [Laura.Gottschalk@fda.hhs.gov]; Wollersheim, Susan [Susan.Wollersheim@fda.hhs.gov]; Lee, Lucia [Lucia.Lee@fda.hhs.gov]; Allende, Maria [Maria.Allende@fda.hhs.gov]; Schwartz, Ann T [Ann.Schwartz@fda.hhs.gov]; Hess, Maureen [Maureen.Hess@fda.hhs.gov]
CC: Yang, Hong (CBER) [hong.yang@fda.hhs.gov]; Funk, Patrick [Patrick.Funk@fda.hhs.gov]; Yogurtcu, Osman [Osman.Yogurtcu@fda.hhs.gov]; Anderson, Steven [Steven.Anderson@fda.hhs.gov]; Welsh, Kerry [Kerry.Welsh@fda.hhs.gov]; Baublatt, Jane [Jane.Baublatt@fda.hhs.gov]; Gomez-Lorenzo, Margarita [Margarita.Gomez-Lorenzo@fda.hhs.gov]
Subject: STN 125742/0 - COMIRNATY - Discussion of Benefit-Risk assessment in 16 to 17 year olds
Attachments: BR for Pfizer 16-17 yr_AUG15_2021.pptx
Location: Zoom; (b)(6)
Start: 8/16/2021 2:00:00 PM
End: 8/16/2021 3:00:00 PM
Show Time As: Tentative

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

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Saturday, August 14, 2021 4:08 PM
To: Naik, Ramachandra; Marks, Peter; Forshee, Richard; Yang, Ye; Nair, Narayan; Niu, Manette; Alimchandani, Meghna; Gruber, Marion; Krause, Philip; Farizo, Karen; Finn, Theresa; Izurieta, Hector; Roberts, Jeff; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Prutzman, Kirk C; Sutkowski, Elizabeth M.; Smith, Michael (CBER); Gottschalk, Laura; Wollersheim, Susan; Lee, Lucia; Allende, Maria; Schwartz, Ann T; Hess, Maureen
Cc: Yang, Hong (CBER); Funk, Patrick; Yogurtcu, Osman; Anderson, Steven; Welsh, Kerry; Baublatt, Jane; Gomez-Lorenzo, Margarita
Subject: STN 125742/0 - COMIRNATY - Discussion of Benefit-Risk assessment in 16 to 17 year olds
When: Monday, August 16, 2021 2:00 PM-3:00 PM (UTC-05:00) Eastern Time (US & Canada).
Where: Zoom; (b)(6)

Update:

The latest version of the benefit-risk assessment slide set (provided by Rich) attached.

This meeting is scheduled to discuss benefit-risk assessment in individuals 16 through 17 years of age related to myocarditis. Dr. Marks, OBE and OVRP are invited to this meeting. Please forward the invite to anyone that I missed.

✕ The linked im...

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Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

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568 8864 (Toll Free)

Meeting
ID:
Passcode:

(b)(6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting
ID:
Passcode:

(b)(6)

SIP:

Passcode

(b)(6)

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/22/2021 9:00:20 AM
To: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]
Subject: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002).docx
Attachments: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002).docx

Highlighting system – red means no, we won't take; yellow, let's discuss; green, should accept. OCC just

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/21/2021 11:23:52 AM
To: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]; Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]]
CC: Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]
Subject: follow-up on Fact Sheet and VIS
Location: Microsoft Teams Meeting
Start: 8/21/2021 12:00:00 PM
End: 8/21/2021 12:30:00 PM
Show Time As: Busy

Required Attendees: Raza, Mark; Tierney, Julia
Optional Attendees: Edmonds, Amanda

Hi all,

We thought it might make sense to have a quick chat about this if you're available.

Mark and Amanda, I am including you both in case one of you can attend. Happy to change the time if this does not work.

Apologies in advance for scheduling a Saturday meeting.

Thanks,

Sana

Microsoft Teams meeting

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(b)(6)

United States, Washington DC

Phone Conference ID: (b)(6)

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From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Saturday, August 21, 2021 9:07 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 9:03 AM

To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:46 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

From my understanding

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:45 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Yes, that section.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:37 AM

To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter

<Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

I think it is, Mark. This is the section you mean, right

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:34 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Sorry – related issue

(b)(5)

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:23 AM

To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

(b)(5)

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:39 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:42 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:36 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda,

We'll work through this. We will just have to find something practical to implement, given this is the worst pandemic in a the century.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 6:08 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Same here- (b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:59 PM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Sana – I'm sorry but I am not exactly sure. (b)(5)

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:38 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: FW: follow-up on Fact Sheet and VIS

Hi Mark,

We were hoping you could help us with the question we posed to Amanda below re: (b)(5)

Any insight would be greatly appreciated.

Sana

From: Hussain, Sana
Sent: Friday, August 20, 2021 2:59 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Amanda,

I know we're still waiting on the okay from CDC, but OVRP had one question as they were reviewing the language in the FS (which they had some clarifying edits, but substantively it remains the same). They are curious re: (b)(5)

(b)(5)

(b)(6)

I think there was some confusion and any insight that you have would be greatly appreciated.

Sorry for the trouble (and I do hope (b)(6) is going okay).

Sana

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:02 AM

To: Malone, Kevin M (CDC) <kmm2@cdc.gov>

Cc: Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>; Thombly, Melisa L (CDC) <fsy1@cdc.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: FW: follow-up on Fact Sheet and VIS

Kevin, as discussed, here is:

(b)(5)

(b)(5)

Please copy Mark and Sana on any reply.

Thanks,
Amanda

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:00 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Thanks so much again for all you help Amanda. Attached is a clean Fact Sheet with the footnote incorporated for where we use the phras (b)(5) for you to forward to CDC.

I hope you (b)(6)!

From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 7/21/2021 8:25:57 AM
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CC: Witten, Celia (CBER) [Celia.Witten@fda.hhs.gov]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Scott, John [John.Scott@fda.hhs.gov]
Subject: BLA STN 125742/0 – COMIRNATY (COVID-19 mRNA Vaccine) - Meeting with Dr. Gruber and Dr. Marks
Attachments: RE: Pfizer BLA COVID-19 vaccine; STN 125742_Pfizer's COVID-19 Vaccine BLA_Review activities and target completion dates.docx
Location: Zoom; (b)(6)
Start: 7/23/2021 11:00:00 AM
End: 7/23/2021 12:00:00 PM
Show Time As: Tentative

Required Attendees: Marks, Peter; Gruber, Marion; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Baldwin, Brenda; Smith, Michael (CBER); Gottschalk, Laura; Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Lee, Shiojwen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Crim, James; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Tang, Xinyu; Yang, Ye; Allende, Maria

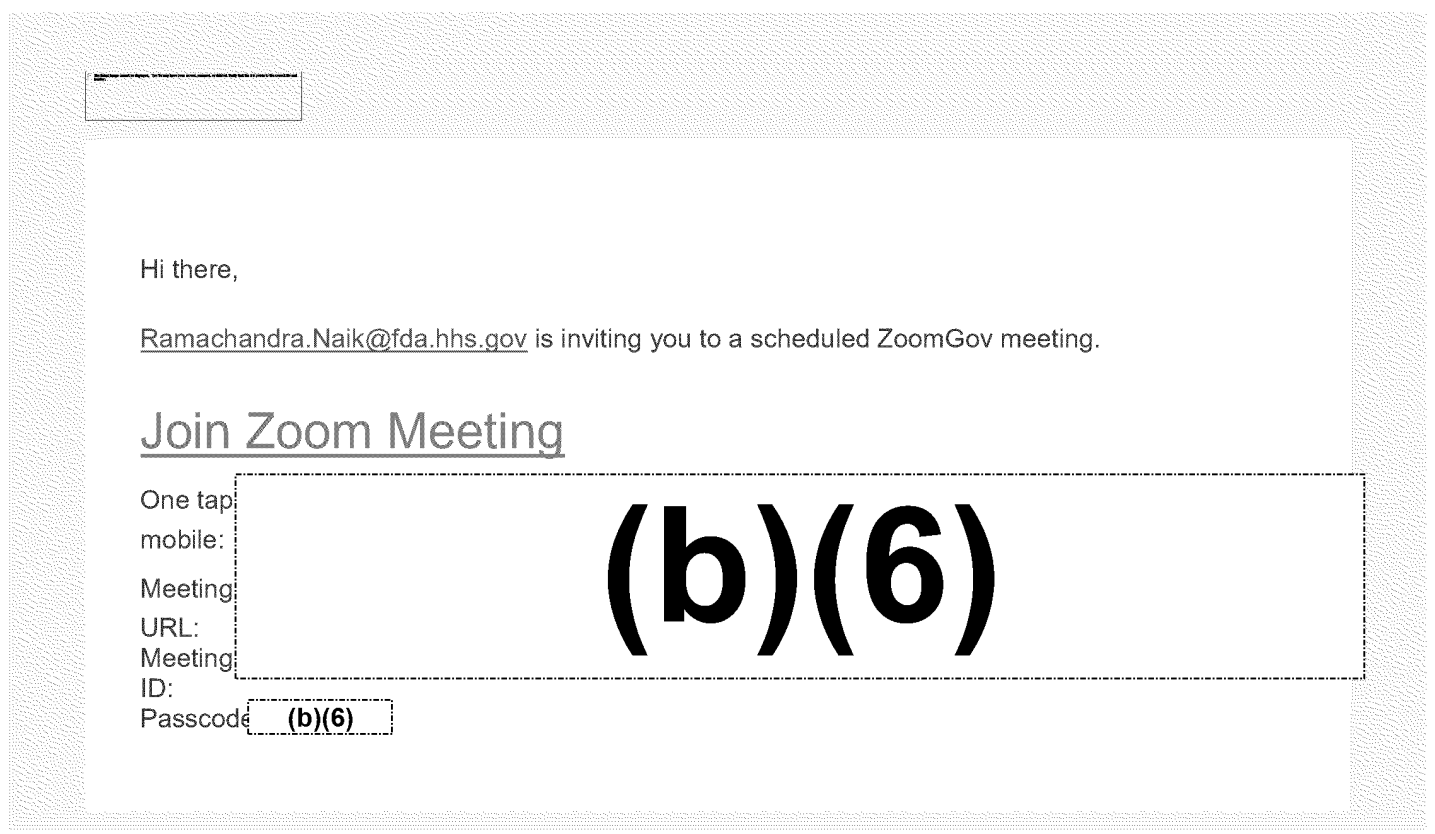
Optional Attendees: Witten, Celia (CBER); Walinsky, Sarah; Scott, John

This meeting with Dr. Gruber and Dr. Marks is scheduled to plan for review of the BLA during Dr. Gruber's (b)(6) and to know Dr. Marks' expectations.

Attached:
Email chain from Drs. Gruber and Marks informing of this meeting
Word document listing BLA review activities and target completion dates

Link to the [BLA STN 125742/0](#) in docuBridge.

Please note as this meeting is being scheduled in a hurry, not all invitees are available at this slot. Please adjust your time or forward to others for representation. Also, please feel free to forward the invite to others if they need to attend and are not included.



Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 669 216 1590 or +1 551 285 1373 or
833 568 8864 (Toll Free)

Meeting ID: **(b)(6)**

ID:

Passcode: **(b)(6)**

International numbers

Join from an H.323/SIP room system

H.323: **(b)(6)** (US West)
(b)(6) (US East)

Meeting ID:

ID:

Passcode:

SIP:

Passcode:

(b)(6)

From: Gottschalk, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9839A4146EF74943B3BD34FADCD29132-LAURA.GOTTS]
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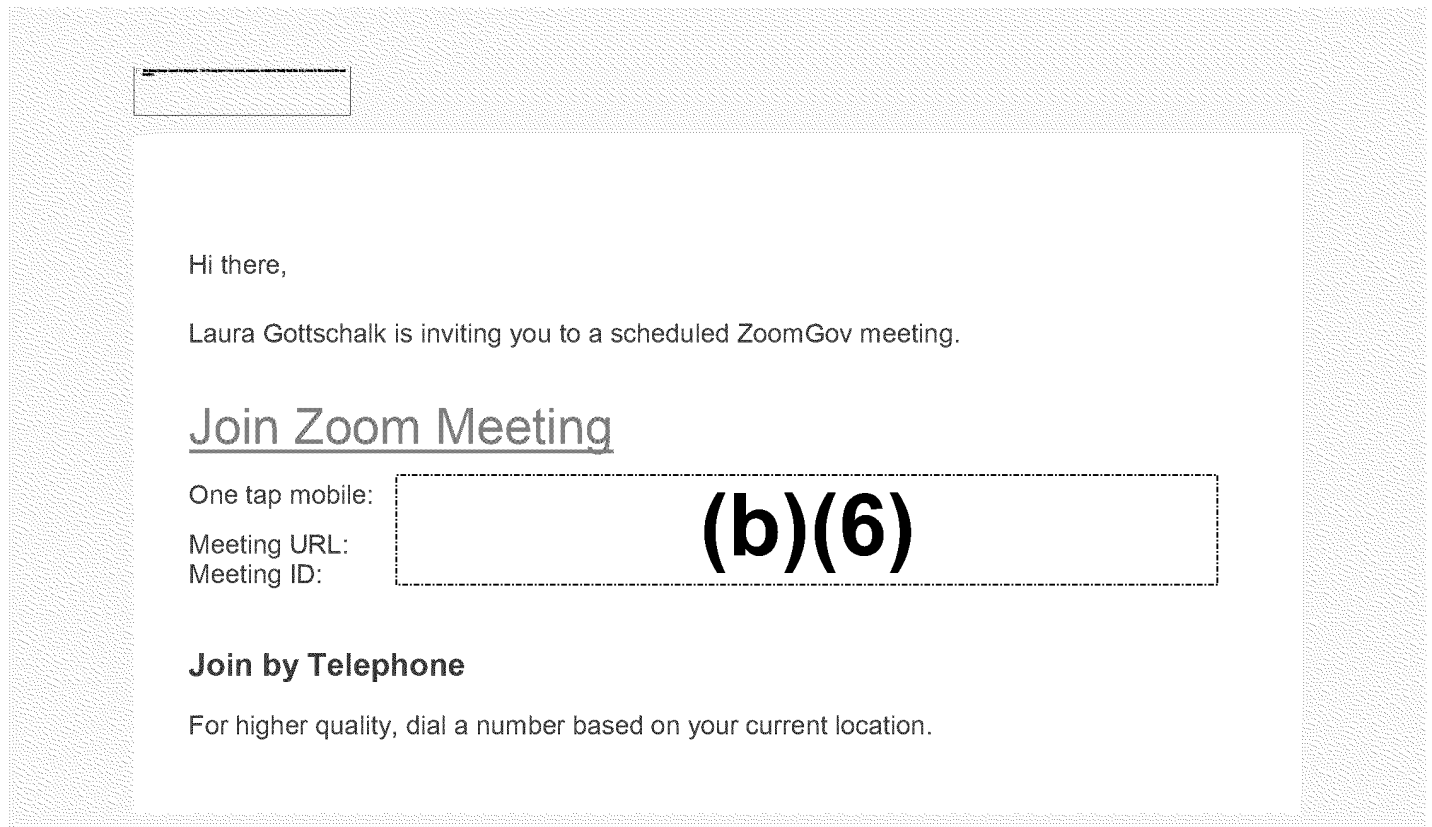
Subject: BLA STN 125742/0 - Weekly Mtg w/Dr. Marks | COMIRNATY, COVID-19 mRNA Vaccine; BioNTech Manufacturing GmbH (w/Pfizer)
Location: Zoom [redacted] (b)(6)
Start: 8/3/2021 4:30:00 PM
End: 8/3/2021 5:00:00 PM
Show Time As: Tentative

Required Attendees: Naik, Ramachandra; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiohjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Gruber, Marion; Kaur, Simleen

Optional Attendees: Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER)

07/28 Update: Time changed due to scheduling conflicts

This is a regular weekly meeting with Dr. Marks to discuss the progress of the COMIRNATY BLA (STN 125742/0).



A screenshot of a Zoom meeting invitation. At the top left, there is a small redacted box. The main body of the invitation contains the following text: "Hi there," followed by "Laura Gottschalk is inviting you to a scheduled ZoomGov meeting." Below this is a large heading "Join Zoom Meeting" with a blue underline. Underneath the heading, there are three lines of text: "One tap mobile:", "Meeting URL:", and "Meeting ID:". Each of these lines is followed by a large redacted box containing the text "(b)(6)". At the bottom of the invitation, there is a section titled "Join by Telephone" in bold, followed by the text "For higher quality, dial a number based on your current location."

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 669 216 1590 or +1
551 285 1373 or 833 568 8864 (Toll Free)

Meeting ID:

(b)(6)

International numbers

Join from an H.323/SIP room system

H.323:

(b)(6)

Meeting ID:

SIP:

From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 8/9/2021 7:40:48 AM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Sutkowski, Elizabeth M. [Elizabeth.Sutkowski@fda.hhs.gov]; McVittie, Loris [Loris.McVittie@fda.hhs.gov]; Prutzman, Kirk C [Kirk.Prutzman@fda.hhs.gov]; Lee, Lucia [Lucia.Lee@fda.hhs.gov]; Allende, Maria [Maria.Allende@fda.hhs.gov]; Fink, Doran [Doran.Fink@fda.hhs.gov]; Pratt, Douglas R. [Douglas.Pratt@fda.hhs.gov]; Peden, Keith [Keith.Peden@fda.hhs.gov]; Weir, Jerry P. [Jerry.Weir@fda.hhs.gov]; Levis, Robin [Robin.Levis@fda.hhs.gov]; Pan, Tao [Tao.Pan@fda.hhs.gov]; Kenney, James [James.Kenney@fda.hhs.gov]; Shahabuddin, Muhammad [Muhammad.Shahabuddin@fda.hhs.gov]; Eichelberger, Maryna [Maryna.Eichelberger@fda.hhs.gov]; Quander III, Joseph [Joseph.Quander@fda.hhs.gov]; Green, Martin (Dave) [Martin.Green@fda.hhs.gov]; Lin, Tsai-Lien [Tsai-Lien.Lin@fda.hhs.gov]; Huang, Lei [Lei.Huang@fda.hhs.gov]; Scott, John [John.Scott@fda.hhs.gov]; Lee, Shiojwen [Shiojwen.Lee@fda.hhs.gov]; Baumblatt, Jane [Jane.Baumblatt@fda.hhs.gov]; Niu, Manette [Manette.Niu@fda.hhs.gov]; Forshee, Richard [Richard.Forshee@fda.hhs.gov]; Nair, Narayan [Narayan.Nair@fda.hhs.gov]; Alimchandani, Meghna [Meghna.Alimchandani@fda.hhs.gov]; Li, Nicole [Nicole.Li@fda.hhs.gov]; Peters, Lori [Lori.Peters@fda.hhs.gov]; Ertel, Donald [Donald.Ertel@fda.hhs.gov]; Crim, James [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3793abc329a4f0f8faee12d3204ff5c-CrimJ]; Eltermann, John [John.Eltermann@fda.hhs.gov]; Renshaw, Carolyn [Carolyn.Renshaw@fda.hhs.gov]; Cato, Dennis [Dennis.Cato@fda.hhs.gov]; Mampilly, Carrie [carrie.Mampilly@fda.hhs.gov]; Stockbridge, Lisa L [Lisa.Stockbridge@fda.hhs.gov]; Sausville, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=514d822e2f744acb987245ae54ae9424-sausville]; Nelle, Timothy [Timothy.Nelle@fda.hhs.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Finn, Theresa [Theresa.Finn@fda.hhs.gov]; Krause, Philip [Philip.Krause@fda.hhs.gov]; Hess, Maureen [Maureen.Hess@fda.hhs.gov]; Welsh, Kerry [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=39b32156b8d34975a1093048aa852589-Kerry.Welsh]; Lorenzo, Anthony [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=eebb907a6aaf4364abc83860b5e9f511-LorenzoA]; Gottschalk, Laura [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9839a4146ef74943b3bd34fadcd29132-Laura.Gotts]; Smith, Michael (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=22f70d8058734aca97200cc280820792-SmithM]; Malarkey, Mary [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=50beada48dce423393136659ef12dec2-malarkey]; Mendoza, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3fd765c3b23b4417be08879adfa40247-Melissa.Men]; Richardson, Anita F (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0264e1cf8edd4b1ebc2ef1eb94a28da4-RichardsonA]; Thompson, Deborah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=3b1daeb32ffc4eb9ad43753eb1af30a2-Deborah.Tho]

Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Daily check-in with Dr. Marks (and the Leadership)

Location: Zoom (b)(6)

Start: 8/9/2021 8:00:00 AM

End: 8/9/2021 8:30:00 AM

Show Time As: Tentative

Recurrence: Daily
every day from 8:00 AM to 8:30 AM

Required Attendees: Marks, Peter; Sutkowski, Elizabeth M.; McVittie, Loris; Prutzman, Kirk C; Lee, Lucia; Allende, Maria; Fink, Doran; Pratt, Douglas R.; Peden, Keith; Weir, Jerry P.; Levis, Robin; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Green, Martin (Dave); Lin, Tsai-Lien; Huang, Lei; Scott, John; Lee, Shiohjen; Baumblatt, Jane; Niu, Manette; Forshee, Richard; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Ertel, Donald; Crim, James; Eltermann, John; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Farizo, Karen; Finn, Theresa; Krause, Philip; Hess, Maureen; Welsh, Kerry; Lorenzo, Anthony; Gottschalk, Laura; Smith, Michael (CBER); Malarkey, Mary; Mendoza, Melissa; Richardson, Anita F (CBER); Thompson, Deborah; Walinsky, Sarah

This meeting is for check-in with Dr. Marks and Leads (Team Leaders, Branch Chiefs, Supervisors and Division Directors) regarding the review progress of the COMIRNATY BLA (STN 125742/0).

Hi there,

Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap
mobile:
Meeting
URL:
Meeting
ID:
Passcode

(b)(6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590 or
833 568 8864 (Toll Free)

Meeting
ID:

(b)(6)

Passcode

International numbers

Join from an H.323/SIP room system

H.323:

Meeting

ID:

Passcode

SIP:

Passcode

(b)(6)

From: Gottschalk, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9839A4146EF74943B3BD34FADCD29132-LAURA.GOTTS]
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[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4cd9d011e02c45d6b1005d46342cad69-Devore]; Marshall, Valerie
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=42f1176fd7ed477f8ec7241d392eaf2c-MarshallV]; Hess, Maureen
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=23ed9c01196f4765b89921c357f855f9-Hessma]; Goud, Ravi
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1b7603ba94e24c089ab4f83e09bcd3c4-Ravi.Goud]; Crim, James
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e3793abc329a4f0f8faee12d3204ff5c-CrimJ]; Gruber, Marion
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]; Kaur, Simleen
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=da08aa1f1e9a48679cf4bb1eee2bf4a8-KaurS]; Forshee, Richard
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=bc6a16c85d124b81893beb85a6929867-Forshee]; Lu, Yun (CBER)
[/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c9243cd05cf2428a8d9ee0f6d7c1b764-LuYu]

CC: Maloney, Diane [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=e59205500e944c9eacc4524ea18ed5bb-MaloneyD]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Witten, Celia (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fc08ebb3ac61486da9f1b4046757c5cf-Witten]; Richardson, Anita F (CBER) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0264e1cf8edd4b1ebc2ef1eb94a28da4-RichardsonA]; Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]

Subject: Canceled: BLA STN 125742/0 - Weekly Mtg w/Dr. Marks | COMIRNATY, COVID-19 mRNA Vaccine; BioNTech Manufacturing GmbH (w/Pfizer)

Start: 8/16/2021 2:30:00 PM

End: 8/16/2021 3:00:00 PM

Show Time As: Free

Importance: High

Required Attendees: Naik, Ramachandra; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiohjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Goud, Ravi; Crim, James; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER)

Optional Attendees: Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Richardson, Anita F (CBER); Hussain, Sana

This meeting has been replaced by the 10:30AM meeting on Friday, August 20.

This is a regular weekly meeting with Dr. Marks to discuss the progress of the COMIRNATY BLA (STN 125742/0).

From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 8/5/2021 6:38:32 PM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]; Gottschalk, Laura [Laura.Gottschalk@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Krause, Philip [Philip.Krause@fda.hhs.gov]; Fink, Doran [Doran.Fink@fda.hhs.gov]; Pratt, Douglas R. [Douglas.Pratt@fda.hhs.gov]; McVittie, Lorin [Lorin.McVittie@fda.hhs.gov]; Wollersheim, Susan [Susan.Wollersheim@fda.hhs.gov]; Lee, Lucia [Lucia.Lee@fda.hhs.gov]; Schwartz, Ann T [Ann.Schwartz@fda.hhs.gov]; Allende, Maria [Maria.Allende@fda.hhs.gov]; Wang, Xiao [Xiao.Wang@fda.hhs.gov]; Cheung, Anissa [Anissa.Cheung@fda.hhs.gov]; Wang, Hsiaoling [Hsiaoling.Wang@fda.hhs.gov]; Yitbarek, Emnet [Emnet.Yitbarek@fda.hhs.gov]; Garcia, Karla [Karla.Garcia@fda.hhs.gov]; Choudhary, Anil [Anil.Choudhary@fda.hhs.gov]; Alvarado, Esmeralda [Esmeralda.Alvarado@fda.hhs.gov]; Anderson, Marie [Marie.Anderson@fda.hhs.gov]; Hulme, Cheryl [Cheryl.Hulme@fda.hhs.gov]; Al-Humadi, Nabil [Nabil.AlHumadi@fda.hhs.gov]; Huang, Lei [Lei.Huang@fda.hhs.gov]; Yang, Ye [Ye.Yang@fda.hhs.gov]; Tang, Xinyu [Xinyu.Tang@fda.hhs.gov]; Thompson, Deborah [Deborah.Thompson@fda.hhs.gov]; Jones, Kathleen (CBER) [Kathleen.Jones1@fda.hhs.gov]; Fontan, Laura [Laura.Fontan@fda.hhs.gov]; Price, Gregory [Gregory.Price@fda.hhs.gov]; Wu, Zhongren [Zhongren.Wu@fda.hhs.gov]; Ertel, Donald [Donald.Ertel@fda.hhs.gov]; Allen, Ekaterina [Ekaterina.Allen@fda.hhs.gov]; Zubkova, Iryna [Iryna.Zubkova@fda.hhs.gov]; Chun, Haecin [Haecin.Chun@fda.hhs.gov]; Elekwachi, Oluchi [Oluchi.Elekwachi@fda.hhs.gov]; Stewart, Daphne [Daphne.Stewart@fda.hhs.gov]; Mendoza, Melissa [Melissa.Mendoza@fda.hhs.gov]; Baldwin, Brenda [Brenda.Baldwin@fda.hhs.gov]; Smith, Michael (CBER) [Michael.Smith2@fda.hhs.gov]; Sutkowski, Elizabeth M. [Elizabeth.Sutkowski@fda.hhs.gov]; Prutzman, Kirk C [Kirk.Prutzman@fda.hhs.gov]; Peden, Keith [Keith.Peden@fda.hhs.gov]; Weir, Jerry P. [Jerry.Weir@fda.hhs.gov]; Levis, Robin [Robin.Levis@fda.hhs.gov]; Overking, Cassandra [Cassandra.Overking@fda.hhs.gov]; Verma, Swati [Swati.Verma@fda.hhs.gov]; Pan, Tao [Tao.Pan@fda.hhs.gov]; Kenney, James [James.Kenney@fda.hhs.gov]; Shahabuddin, Muhammad [Muhammad.Shahabuddin@fda.hhs.gov]; Eichelberger, Maryna [Maryna.Eichelberger@fda.hhs.gov]; Quander III, Joseph [Joseph.Quander@fda.hhs.gov]; Eltermann, John [John.Eltermann@fda.hhs.gov]; Green, Martin (Dave) [Martin.Green@fda.hhs.gov]; Lin, Tsai-Lien [Tsai-Lien.Lin@fda.hhs.gov]; Scott, John [John.Scott@fda.hhs.gov]; Lee, Shioowjen [Shioowjen.Lee@fda.hhs.gov]; Baublatt, Jane [Jane.Baublatt@fda.hhs.gov]; Niu, Manette [Manette.Niu@fda.hhs.gov]; Nair, Narayan [Narayan.Nair@fda.hhs.gov]; Alimchandani, Meghna [Meghna.Alimchandani@fda.hhs.gov]; Li, Nicole [Nicole.Li@fda.hhs.gov]; Peters, Lori [Lori.Peters@fda.hhs.gov]; Renshaw, Carolyn [Carolyn.Renshaw@fda.hhs.gov]; Cato, Dennis [Dennis.Cato@fda.hhs.gov]; Mampilly, Carrie [carrie.Mampilly@fda.hhs.gov]; Jones, Dana [Dana.Jones@fda.hhs.gov]; Stockbridge, Lisa L [Lisa.Stockbridge@fda.hhs.gov]; Nelle, Timothy [Timothy.Nelle@fda.hhs.gov]; Malarkey, Mary [Mary.Malarkey@fda.hhs.gov]; Anderson, Steven [Steven.Anderson@fda.hhs.gov]; Finn, Theresa [Theresa.Finn@fda.hhs.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Roberts, Jeff [Jeff.Roberts@fda.hhs.gov]; Izurieta, Hector [Hector.Izurieta@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Rouse, David [David.Rouse@fda.hhs.gov]; Devore, Nicolette [Nicolette.Devore@fda.hhs.gov]; Marshall, Valerie [valerie.Marshall@fda.hhs.gov]; Hess, Maureen [Maureen.Hess@fda.hhs.gov]; Gruber, Marion [Marion.Gruber@fda.hhs.gov]; Kaur, Simleen [Simleen.Kaur@fda.hhs.gov]; Forshee, Richard [Richard.Forshee@fda.hhs.gov]; Lu, Yun (CBER) [Yun.Lu@fda.hhs.gov]; Sausville, Robert [Robert.Sausville@fda.hhs.gov]; Maloney, Diane [Diane.Maloney@fda.hhs.gov]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Witten, Celia (CBER) [Celia.Witten@fda.hhs.gov]; Welsh, Kerry [Kerry.Welsh@fda.hhs.gov]; Zinderman, Craig E [Craig.Zinderman@fda.hhs.gov]; Hussey, Deirdre [Deirdre.Hussey@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Richardson, Anita F (CBER) [Anita.Richardson@fda.hhs.gov]
CC: Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]; Kaelber, Nadine [Nadine.Kaelber@fda.hhs.gov]; Taylor, Leslie [Leslie.Taylor@fda.hhs.gov]
Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Meeting with Dr. Marks (entire review team)
Location: Zoom; (b)(6)
Start: 8/13/2021 2:30:00 PM
End: 8/13/2021 3:30:00 PM

Show Time As: Busy

Required Attendees: Gottschalk, Laura; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiohjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert; Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Hussey, Deirdre; McNeill, Lorrie; Richardson, Anita F (CBER)

Optional Attendees: Frantz-Bohn, Susan (Susan.Frantzbohn@fda.hhs.gov); Kaelber, Nadine; Taylor, Leslie

This meeting is rescheduled to start 30 minutes later as it overlaps with [ACIP discussion](#) on Considerations for booster doses of COVID-19 vaccines as many folks will want to listen in on the ACIP discussion.

Rescheduled because of conflicts.

This meeting with Dr. Marks is to discuss the review progress of the COMIRNATY BLA (STN 125742/0) with the entire review team, and to provide updates.

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From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 8/13/2021 2:05:09 PM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]; Gottschalk, Laura [Laura.Gottschalk@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Gruber, Marion [Marion.Gruber@fda.hhs.gov]; Krause, Philip [Philip.Krause@fda.hhs.gov]; Fink, Doran [Doran.Fink@fda.hhs.gov]; Pratt, Douglas R. [Douglas.Pratt@fda.hhs.gov]; McVittie, Loris [Loris.McVittie@fda.hhs.gov]; Wollersheim, Susan [Susan.Wollersheim@fda.hhs.gov]; Lee, Lucia [Lucia.Lee@fda.hhs.gov]; Schwartz, Ann T [Ann.Schwartz@fda.hhs.gov]; Allende, Maria [Maria.Allende@fda.hhs.gov]; Wang, Xiao [Xiao.Wang@fda.hhs.gov]; Cheung, Anissa [Anissa.Cheung@fda.hhs.gov]; Wang, Hsiaoling [Hsiaoling.Wang@fda.hhs.gov]; Yitbarek, Emnet [Emnet.Yitbarek@fda.hhs.gov]; Garcia, Karla [Karla.Garcia@fda.hhs.gov]; Choudhary, Anil [Anil.Choudhary@fda.hhs.gov]; Alvarado, Esmeralda [Esmeralda.Alvarado@fda.hhs.gov]; Anderson, Marie [Marie.Anderson@fda.hhs.gov]; Hulme, Cheryl [Cheryl.Hulme@fda.hhs.gov]; Al-Humadi, Nabil [Nabil.AlHumadi@fda.hhs.gov]; Huang, Lei [Lei.Huang@fda.hhs.gov]; Yang, Ye [Ye.Yang@fda.hhs.gov]; Tang, Xinyu [Xinyu.Tang@fda.hhs.gov]; Thompson, Deborah [Deborah.Thompson@fda.hhs.gov]; Jones, Kathleen (CBER) [Kathleen.Jones1@fda.hhs.gov]; Fontan, Laura [Laura.Fontan@fda.hhs.gov]; Price, Gregory [Gregory.Price@fda.hhs.gov]; Wu, Zhongren [Zhongren.Wu@fda.hhs.gov]; Ertel, Donald [Donald.Ertel@fda.hhs.gov]; Allen, Ekaterina [Ekaterina.Allen@fda.hhs.gov]; Zubkova, Iryna [Iryna.Zubkova@fda.hhs.gov]; Chun, Haecin [Haecin.Chun@fda.hhs.gov]; Elekwachi, Oluchi [Oluchi.Elekwachi@fda.hhs.gov]; Stewart, Daphne [Daphne.Stewart@fda.hhs.gov]; Mendoza, Melissa [Melissa.Mendoza@fda.hhs.gov]; Baldwin, Brenda [Brenda.Baldwin@fda.hhs.gov]; Smith, Michael (CBER) [Michael.Smith2@fda.hhs.gov]; Sutkowski, Elizabeth M. [Elizabeth.Sutkowski@fda.hhs.gov]; Prutzman, Kirk C [Kirk.Prutzman@fda.hhs.gov]; Peden, Keith [Keith.Peden@fda.hhs.gov]; Weir, Jerry P. [Jerry.Weir@fda.hhs.gov]; Levis, Robin [Robin.Levis@fda.hhs.gov]; Overking, Cassandra [Cassandra.Overking@fda.hhs.gov]; Verma, Swati [Swati.Verma@fda.hhs.gov]; Pan, Tao [Tao.Pan@fda.hhs.gov]; Kenney, James [James.Kenney@fda.hhs.gov]; Shahabuddin, Muhammad [Muhammad.Shahabuddin@fda.hhs.gov]; Eichelberger, Maryna [Maryna.Eichelberger@fda.hhs.gov]; Quander III, Joseph [Joseph.Quander@fda.hhs.gov]; Eltermann, John [John.Eltermann@fda.hhs.gov]; Green, Martin (Dave) [Martin.Green@fda.hhs.gov]; Lin, Tsai-Lien [Tsai-Lien.Lin@fda.hhs.gov]; Scott, John [John.Scott@fda.hhs.gov]; Lee, Shiojwen [Shiojwen.Lee@fda.hhs.gov]; Baumblatt, Jane [Jane.Baumblatt@fda.hhs.gov]; Niu, Manette [Manette.Niu@fda.hhs.gov]; Nair, Narayan [Narayan.Nair@fda.hhs.gov]; Alimchandani, Meghna [Meghna.Alimchandani@fda.hhs.gov]; Li, Nicole [Nicole.Li@fda.hhs.gov]; Peters, Lori [Lori.Peters@fda.hhs.gov]; Renshaw, Carolyn [Carolyn.Renshaw@fda.hhs.gov]; Cato, Dennis [Dennis.Cato@fda.hhs.gov]; Mampilly, Carrie [carrie.Mampilly@fda.hhs.gov]; Jones, Dana [Dana.Jones@fda.hhs.gov]; Stockbridge, Lisa L [Lisa.Stockbridge@fda.hhs.gov]; Nelle, Timothy [Timothy.Nelle@fda.hhs.gov]; Malarkey, Mary [Mary.Malarkey@fda.hhs.gov]; Anderson, Steven [Steven.Anderson@fda.hhs.gov]; Finn, Theresa [Theresa.Finn@fda.hhs.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Roberts, Jeff [Jeff.Roberts@fda.hhs.gov]; Izurieta, Hector [Hector.Izurieta@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Rouse, David [David.Rouse@fda.hhs.gov]; Devore, Nicolette [Nicolette.Devore@fda.hhs.gov]; Marshall, Valerie [valerie.Marshall@fda.hhs.gov]; Hess, Maureen [Maureen.Hess@fda.hhs.gov]; Kaur, Simleen [Simleen.Kaur@fda.hhs.gov]; Forshee, Richard [Richard.Forshee@fda.hhs.gov]; Lu, Yun (CBER) [Yun.Lu@fda.hhs.gov]; Sausville, Robert [Robert.Sausville@fda.hhs.gov]; Maloney, Diane [Diane.Maloney@fda.hhs.gov]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Witten, Celia (CBER) [Celia.Witten@fda.hhs.gov]; Welsh, Kerry [Kerry.Welsh@fda.hhs.gov]; Zinderman, Craig E [Craig.Zinderman@fda.hhs.gov]; Hussey, Deirdre [Deirdre.Hussey@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Richardson, Anita F (CBER) [Anita.Richardson@fda.hhs.gov]
CC: Frantz-Bohn, Susan [Susan.Frantzbohn@fda.hhs.gov]; Kaelber, Nadine [Nadine.Kaelber@fda.hhs.gov]; Taylor, Leslie [Leslie.Taylor@fda.hhs.gov]; Kong, Hyesuk [Hyesuk.Kong@fda.hhs.gov]; Hussain, Sana [Sana.Hussain@fda.hhs.gov]
Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Meeting with Dr. Marks (entire review team)
Location: Zoom [REDACTED] (b)(6)
Start: 8/20/2021 10:30:00 AM
End: 8/20/2021 11:30:00 AM

Show Time As: Tentative

Required Attendees: Naik, Ramachandra; Gottschalk, Laura; Marks, Peter; Gruber, Marion; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiojjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert; Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Hussey, Deirdre; McNeill, Lorrie; Richardson, Anita F (CBER)

Optional Attendees: Frantz-Bohn, Susan (Susan.Frantzbohn@fda.hhs.gov); Kaelber, Nadine; Taylor, Leslie; Kong, Hyesuk; Hussain, Sana

This meeting with Dr. Marks is to discuss the review progress of the COMIRNATY BLA (STN 125742/0) with the entire review team, and to provide updates.

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From: Gottschalk, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9839A4146EF74943B3BD34FADCD29132-LAURA.GOTTS]
Sent: 8/23/2021 8:28:01 AM
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Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - Team meeting

Location: (b)(6)

Start: 8/23/2021 8:45:00 AM

End: 8/23/2021 9:00:00 AM

Show Time As: Tentative

Required Attendees: Naik, Ramachandra; Gottschalk, Laura; Marks, Peter; Gruber, Marion; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiowjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert; Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Hussey, Deirdre; McNeill, Lorrie; Richardson, Anita F (CBER); Frantz-Bohn, Susan; Kaelber, Nadine; Taylor, Leslie; Kong, Hyesuk; Hussain, Sana; Emerson, Debra; Jackson, Susan M

This is a COMIRNATY Flash Team meeting to discuss the rest of the day (only good news ☺)

[Redacted]

Hi there,

Laura Gottschalk is inviting you to a scheduled ZoomGov meeting.

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(b)(6)

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From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 7/21/2021 8:25:57 AM
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CC:

Subject: BLA STN 125742/0 – COMIRNATY (COVID-19 mRNA Vaccine) - Meeting with Dr. Gruber and Dr. Marks
Attachments: RE: Pfizer BLA COVID-19 vaccine; STN 125742_Pfizer's COVID-19 Vaccine BLA_Review activities and target completion dates.docx

Location: Zoom

(b)(6)

Start: 7/23/2021 11:00:00 AM

End: 7/23/2021 12:00:00 PM

Show Time As: Busy

Required Attendees: Marks, Peter; Gruber, Marion; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Baldwin, Brenda; Smith, Michael (CBER); Gottschalk, Laura; Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Lee, Shiojwen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Crim, James; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Tang, Xinyu; Yang, Ye; Allende, Maria

Optional Attendees: Witten, Celia (CBER); Walinsky, Sarah; Scott, John; Goud, Ravi

Agenda:

1. **Introduction and update by Chair (10 minutes)**
2. **Status update by reviewers (30 minutes)**
3. **Address/Advice by management (20 minutes)**

This meeting with Dr. Gruber and Dr. Marks is scheduled to plan for review of the BLA during Dr. Gruber's and to know Dr. Marks' expectations.

(b)(6)

Attached:

Email chain from Drs. Gruber and Marks informing of this meeting
Word document listing BLA review activities and target completion dates

Link to the [BLA STN 125742/0](#) in docuBridge.

Please note as this meeting is being scheduled in a hurry, not all invitees are available at this slot. Please adjust your time or forward to others for representation. Also, please feel free to forward the invite to others if they need to attend and are not included.

[Redacted]

Hi there,

Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

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From: Gottschalk, Laura [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9839A4146EF74943B3BD34FADCD29132-LAURA.GOTTS]
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Subject: Canceled: BLA STN 125742/0 - Weekly Mtg w/Dr. Marks | COMIRNATY, COVID-19 mRNA Vaccine; BioNTech Manufacturing GmbH (w/Pfizer)

Start: 8/10/2021 4:00:00 PM

End: 8/10/2021 4:30:00 PM

Show Time As: Free

Importance: High

Required Attendees: Naik, Ramachandra; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiowjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Goud, Ravi; Crim, James; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER)

Optional Attendees: Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Richardson, Anita F (CBER)

This meeting has been replaced by the meeting scheduled for 2:00pm Friday, August 13.

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Subject: Canceled: BLA STN 125742/0 - Weekly Mtg w/Dr. Marks | COMIRNATY, COVID-19 mRNA Vaccine; BioNTech Manufacturing GmbH (w/Pfizer)

Start: 8/24/2021 1:00:00 PM

End: 8/24/2021 1:30:00 PM

Show Time As: Free

Importance: High

Required Attendees: Naik, Ramachandra; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiowjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Goud, Ravi; Crim, James; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER)

Optional Attendees: Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Richardson, Anita F (CBER); Hussain, Sana

This is a regular weekly meeting with Dr. Marks to discuss the progress of the COMIRNATY BLA (STN 125742/0).

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Subject: Canceled: BLA STN 125742/0 - Weekly Mtg w/Dr. Marks | COMIRNATY, COVID-19 mRNA Vaccine; BioNTech Manufacturing GmbH (w/Pfizer)

Location: Zoom:

Start: 8/3/2021 4:30:00 PM

End: 8/3/2021 5:00:00 PM

Show Time As: Free

Importance: High

Required Attendees: Naik, Ramachandra; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiohjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER)

Optional Attendees: Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER)

This meeting is being replaced by the meeting scheduled on Aug 6, 4:00-4:30pm

This is a regular weekly meeting with Dr. Marks to discuss the progress of the COMIRNATY BLA (STN 125742/0).

From: Naik, Ramachandra [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=6F65CA32552F4CDAB961DAE0D4576981-NAIKR]
Sent: 7/30/2021 1:24:43 PM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]; Gottschalk, Laura [Laura.Gottschalk@fda.hhs.gov]; Marks, Peter [Peter.Marks@fda.hhs.gov]; Krause, Philip [Philip.Krause@fda.hhs.gov]; Fink, Doran [Doran.Fink@fda.hhs.gov]; Pratt, Douglas R. [Douglas.Pratt@fda.hhs.gov]; McVittie, Loris [Loris.McVittie@fda.hhs.gov]; Wollersheim, Susan [Susan.Wollersheim@fda.hhs.gov]; Lee, Lucia [Lucia.Lee@fda.hhs.gov]; Schwartz, Ann T [Ann.Schwartz@fda.hhs.gov]; Allende, Maria [Maria.Allende@fda.hhs.gov]; Wang, Xiao [Xiao.Wang@fda.hhs.gov]; Cheung, Anissa [Anissa.Cheung@fda.hhs.gov]; Wang, Hsiaoling [Hsiaoling.Wang@fda.hhs.gov]; Yitbarek, Emnet [Emnet.Yitbarek@fda.hhs.gov]; Garcia, Karla [Karla.Garcia@fda.hhs.gov]; Choudhary, Anil [Anil.Choudhary@fda.hhs.gov]; Alvarado, Esmeralda [Esmeralda.Alvarado@fda.hhs.gov]; Anderson, Marie [Marie.Anderson@fda.hhs.gov]; Hulme, Cheryl [Cheryl.Hulme@fda.hhs.gov]; Al-Humadi, Nabil [Nabil.AlHumadi@fda.hhs.gov]; Huang, Lei [Lei.Huang@fda.hhs.gov]; Yang, Ye [Ye.Yang@fda.hhs.gov]; Tang, Xinyu [Xinyu.Tang@fda.hhs.gov]; Thompson, Deborah [Deborah.Thompson@fda.hhs.gov]; Jones, Kathleen (CBER) [Kathleen.Jones1@fda.hhs.gov]; Fontan, Laura [Laura.Fontan@fda.hhs.gov]; Price, Gregory [Gregory.Price@fda.hhs.gov]; Wu, Zhongren [Zhongren.Wu@fda.hhs.gov]; Ertel, Donald [Donald.Ertel@fda.hhs.gov]; Allen, Ekaterina [Ekaterina.Allen@fda.hhs.gov]; Zubkova, Iryna [Iryna.Zubkova@fda.hhs.gov]; Chun, Haecin [Haecin.Chun@fda.hhs.gov]; Elekwachi, Oluchi [Oluchi.Elekwachi@fda.hhs.gov]; Stewart, Daphne [Daphne.Stewart@fda.hhs.gov]; Mendoza, Melissa [Melissa.Mendoza@fda.hhs.gov]; Baldwin, Brenda [Brenda.Baldwin@fda.hhs.gov]; Smith, Michael (CBER) [Michael.Smith2@fda.hhs.gov]; Sutkowski, Elizabeth M. [Elizabeth.Sutkowski@fda.hhs.gov]; Prutzman, Kirk C [Kirk.Prutzman@fda.hhs.gov]; Peden, Keith [Keith.Peden@fda.hhs.gov]; Weir, Jerry P. [Jerry.Weir@fda.hhs.gov]; Levis, Robin [Robin.Levis@fda.hhs.gov]; Overking, Cassandra [Cassandra.Overking@fda.hhs.gov]; Verma, Swati [Swati.Verma@fda.hhs.gov]; Pan, Tao [Tao.Pan@fda.hhs.gov]; Kenney, James [James.Kenney@fda.hhs.gov]; Shahabuddin, Muhammad [Muhammad.Shahabuddin@fda.hhs.gov]; Eichelberger, Maryna [Maryna.Eichelberger@fda.hhs.gov]; Quander III, Joseph [Joseph.Quander@fda.hhs.gov]; Eltermann, John [John.Eltermann@fda.hhs.gov]; Green, Martin (Dave) [Martin.Green@fda.hhs.gov]; Lin, Tsai-Lien [Tsai-Lien.Lin@fda.hhs.gov]; Scott, John [John.Scott@fda.hhs.gov]; Lee, Shiojwen [Shiojwen.Lee@fda.hhs.gov]; Baublatt, Jane [Jane.Baublatt@fda.hhs.gov]; Niu, Manette [Manette.Niu@fda.hhs.gov]; Nair, Narayan [Narayan.Nair@fda.hhs.gov]; Alimchandani, Meghna [Meghna.Alimchandani@fda.hhs.gov]; Li, Nicole [Nicole.Li@fda.hhs.gov]; Peters, Lori [Lori.Peters@fda.hhs.gov]; Renshaw, Carolyn [Carolyn.Renshaw@fda.hhs.gov]; Cato, Dennis [Dennis.Cato@fda.hhs.gov]; Mampilly, Carrie [carrie.Mampilly@fda.hhs.gov]; Jones, Dana [Dana.Jones@fda.hhs.gov]; Stockbridge, Lisa L [Lisa.Stockbridge@fda.hhs.gov]; Nelle, Timothy [Timothy.Nelle@fda.hhs.gov]; Malarkey, Mary [Mary.Malarkey@fda.hhs.gov]; Anderson, Steven [Steven.Anderson@fda.hhs.gov]; Finn, Theresa [Theresa.Finn@fda.hhs.gov]; Farizo, Karen [Karen.Farizo@fda.hhs.gov]; Roberts, Jeff [Jeff.Roberts@fda.hhs.gov]; Izurieta, Hector [Hector.Izurieta@fda.hhs.gov]; Cho, David S (CBER) [David.Cho@fda.hhs.gov]; Rouse, David [David.Rouse@fda.hhs.gov]; Devore, Nicolette [Nicolette.Devore@fda.hhs.gov]; Marshall, Valerie [valerie.Marshall@fda.hhs.gov]; Hess, Maureen [Maureen.Hess@fda.hhs.gov]; Gruber, Marion [Marion.Gruber@fda.hhs.gov]; Kaur, Simleen [Simleen.Kaur@fda.hhs.gov]; Forshee, Richard [Richard.Forshee@fda.hhs.gov]; Lu, Yun (CBER) [Yun.Lu@fda.hhs.gov]; Sausville, Robert [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=514d822e2f744acb987245ae54ae9424-sausville]
CC: Maloney, Diane [Diane.Maloney@fda.hhs.gov]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Witten, Celia (CBER) [Celia.Witten@fda.hhs.gov]; Welsh, Kerry [Kerry.Welsh@fda.hhs.gov]; Zinderman, Craig E [Craig.Zinderman@fda.hhs.gov]; Hussey, Deirdre [Deirdre.Hussey@fda.hhs.gov]; McNeill, Lorrie [Lorrie.McNeill@fda.hhs.gov]; Richardson, Anita F (CBER) [Anita.Richardson@fda.hhs.gov]
Subject: BLA STN 125742/0 - COMIRNATY (COVID-19 Vaccine, mRNA) - BioNTech Manufacturing GmbH (with Pfizer) - Follow-up meeting with Dr. Marks
Location: Zoom [REDACTED] (b)(6)
Start: 8/6/2021 4:00:00 PM
End: 8/6/2021 4:30:00 PM
Show Time As: Busy

Required Attendees:

Naik, Ramachandra; Gottschalk, Laura; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Mendoza, Melissa; Baldwin, Brenda; Smith, Michael (CBER); Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiojwen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Gruber, Marion; Kaur, Simleen; Forshee, Richard; Lu, Yun (CBER); Sausville, Robert

Optional Attendees:

Maloney, Diane; Walinsky, Sarah; Witten, Celia (CBER); Welsh, Kerry; Zinderman, Craig E; Deirdre Hussey; McNeill, Lorrie; Richardson, Anita F (CBER)

This meeting with Dr. Marks is to discuss the review progress of the COMIRNATY BLA (STN 125742/0), and to provide updates.



Hi there,

Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap
mobile:

Meeting
URL:
Meeting
ID:
Passcode

(b)(6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590 or 833
568 8864 (Toll Free)

Meeting **(b)(6)**

ID:

Passcode **(b)(6)**

International numbers

Join from an H.323/SIP room system

H.323:

Meeting

ID:

Passcode:

SIP:

Passcode:

(b)(6)

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 7/21/2021 12:10:03 PM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Julie,

I vote no. Thanks.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

I'm attaching my summary of the meeting for your records. Please let me know if you would like me to circulate to Marion.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 11:59 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet and Peter,

The following summarizes my understanding of the July 19, 2021, 8:30 am meeting held between you, Phil Krause, Julie Tierney and myself to discuss the review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine. During this meeting, I made reference to the memo that Dr. Krause and I composed and sent to Dr. Marks on July 15, 2021, delineating OVR's rationale for why the review timeline and target action due date, September 15, 2021, for this BLA cannot be compressed further. To recap, that memo stated that the review requires a thorough evaluation and FDA's own analysis of the safety, effectiveness and manufacturing information submitted to support licensure of this vaccine. This has been OVR's standard for all other BLAs, and while time-consuming, OVR believes that public confidence in COVID-19 vaccines would not be served by rushing our review and evaluation of the submitted data. In addition, Dr. Krause and I pointed out the very important regulatory issues that still need to be settled by the time we take action on this BLA—including the pediatric plan — which is becoming increasingly complex in light of increasing evidence of association of this vaccine and development of myocarditis (especially in young males, but also ages included in the BLA indication). This also impacts the finalization of post-marketing requirements and post-marketing commitments. In addition, there are pending information requests to the sponsor, and there will likely be additional information requests based on ongoing review of the data, and the timing of the sponsor response is beyond CBER control.

I reiterated during our meeting that OVRP is targeting September 15, 2021, as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this complex BLA with a large amount of data, in a third of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application. In response to your questions, I described OVRP's BLA review assignment processes. I emphasized that for this particular BLA, we assigned two experienced medical officers to this file who are working closely with the data analytics team in CDER-OCS and three statisticians from CBER/OBE who are supporting these review efforts. I did not emphasize this during our meeting, but you should also know that our typical review process includes frequent formal and informal communications with managers at all levels and other OVRP experts not directly assigned to the review team. I reiterated that adding staff to this review at this advanced stage would likely slow down the review due to the need to bring new people up to speed. You inquired whether we need additional help and also asked about the expertise of MOs assigned to this file noting that there would be staff in FDA, e.g., pediatric cardiologist that could assist in the review. You expressed concern about the rising COVID-cases in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized vaccine would be more inclined to get immunized when the product is licensed. You emphasized your interest in licensing this vaccine as soon as possible—a goal that we agree with. We too are concerned about the rising COVID-19 cases in the US, however, our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.

You informed us of your decision that OVRP management and oversight of the BLA review will be delegated to Dr. Marks who will provide you with weekly updates on the review process and ensure that due diligence is exercised while I am away (b)(6). You also informed me that Dr. Krause will not be involved in the BLA oversight as he will be overseeing other regulatory and programmatic programs in OVRP. I expressed my disagreement with these decisions because standard procedures are for the deputy Office Director to assume an Acting Role when the Office Director is out of the Office. I note that Dr. Krause is a recognized expert in vaccine regulation, development and very familiar with the scientific and clinical issues presented by this specific vaccine product and that the review team relies on his expertise and guidance.

I would also like to emphasize OVRP staff's dedication and experience in promoting public health by making safe and effective vaccines available for use in the United States. Since I believe we all agree in the importance both of a rapid decision and a thorough scientific and credible review, Dr. Krause and the OVRP staff will stand ready to assist in any way possible to achieve both of these goals. Please confirm that this summary reflects your recollection of this meeting. If it does not, I would appreciate your letting me know any specific areas where your recollection is different.

Thank you,
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov



From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 7/21/2021 1:38:53 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: FW: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Draft email for your consideration:

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:26 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet,

I leave it to you, but I would consider a high level response correcting Marion's September 15th assertion, unless you agree with it (since this will almost certainly be FOIA'ed and will end up as part of a congressional). Something along the lines that you appreciate the excellent work of the office of vaccines, but that we are experiencing a once in a lifetime pandemic that forces us to challenge how we have done things previously – we need to challenge ourselves to do maximally expedite a high quality review, particularly since you are offering up all of the relevant resources that the agency can potentially provide.

Frankly, I am happy to go on the record here to note that though I understand the exhaustion that some are feeling, the lack of urgency and responsiveness to the public health imperative to save lives that seems to be felt by some in

leadership of the Office of Vaccines is highly disappointing to me. That is my problem, and I will deal with it in due course.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:09 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

(b)(5)

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

I'm attaching my summary of the meeting for your records. Please let me know if you would like me to circulate to Marion.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 11:59 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet and Peter,

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in less than half the time allocated for a priority review application. In response to your questions, I described OVR's BLA review assignment processes. I emphasized that for this particular BLA, we assigned two experienced medical officers to this file who are working closely with the data analytics team in CDER-OCS and three statisticians from CBER/OBE who are supporting these review efforts. I did not emphasize this during our meeting, but you should also know that our typical review process includes frequent formal and informal communications with managers at all levels and other OVR experts not directly assigned to the review team. I reiterated that adding staff to this review at this advanced stage would likely slow down the review due to the need to bring new people up to speed. You inquired whether we need additional help and also asked about the expertise of MOs assigned to this file noting that there would be staff in FDA, e.g., pediatric cardiologist that could assist in the review. You expressed concern about the rising COVID-cases in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized vaccine would be more inclined to get immunized when the product is licensed. You emphasized your interest in licensing this vaccine as soon as possible—a goal that we agree with. We too are concerned about the rising COVID-19 cases in the US, however, our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.

You informed us of your decision that OVR management and oversight of the BLA review will be delegated to Dr. Marks who will provide you with weekly updates on the review process and ensure that due diligence is exercised while I am away. (b)(6) You also informed me that Dr. Krause will not be involved in the BLA oversight as he will be overseeing other regulatory and programmatic programs in OVR. I expressed my disagreement with these decisions because standard procedures are for the deputy Office Director to assume an Acting Role when the Office Director is out of the Office. I note that Dr. Krause is a recognized expert in vaccine regulation, development and very familiar with the scientific and clinical issues presented by this specific vaccine product and that the review team relies on his expertise and guidance.

I would also like to emphasize OVR staff's dedication and experience in promoting public health by making safe and effective vaccines available for use in the United States. Since I believe we all agree in the importance both of a rapid decision and a thorough scientific and credible review, Dr. Krause and the OVR staff will stand ready to assist in any way possible to achieve both of these goals. Please confirm that this summary reflects your recollection of this meeting. If it does not, I would appreciate your letting me know any specific areas where your recollection is different.

Thank you,
Marion

Marion F. Gruber, Ph.D
Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856
Email: marion.gruber@fda.hhs.gov



From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 7/21/2021 1:45:42 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Draft email for your consideration (bracketed/highlighted language that I'm less certain about including):

(b)(5)

Janet

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 1:27 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: Re: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Ok. Jw

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 1:03:27 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

JW – I will draft a response for your consideration and then peter can follow with his response

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:26 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet,

I leave it to you, but I would consider a high level response correcting Marion's September 15th assertion, unless you agree with it (since this will almost certainly be FOIA'ed and will end up as part of a congressional). Something along the lines that you appreciate the excellent work of the office of vaccines, but that we are experiencing a once in a lifetime pandemic that forces us to challenge how we have done things previously – we need to challenge ourselves to do maximally expedite a high quality review, particularly since you are offering up all of the relevant resources that the agency can potentially provide.

Frankly, I am happy to go on the record here to note that though I understand the exhaustion that some are feeling, the lack of urgency and responsiveness to the public health imperative to save lives that seems to be felt by some in leadership of the Office of Vaccines is highly disappointing to me. That is my problem, and I will deal with it in due course.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:09 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

(b)(5)

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 12:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

I'm attaching my summary of the meeting for your records. Please let me know if you would like me to circulate to Marion.

From: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 11:59 AM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Krause, Philip <Philip.Krause@fda.hhs.gov>
Subject: Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Janet and Peter,

The following summarizes my understanding of the July 19, 2021, 8:30 am meeting held between you, Phil Krause, Julie Tierney and myself to discuss the review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine. During this meeting, I made reference to the memo that Dr. Krause and I composed and sent to Dr. Marks on July 15, 2021, delineating OVRR's rationale for why the review timeline and target action due date, September 15, 2021, for this BLA cannot be compressed further. To recap, that memo stated that the review requires a thorough evaluation and FDA's own analysis of the safety, effectiveness and manufacturing information submitted to support licensure of this vaccine. This has been OVRR's standard for all other BLAs, and while time-consuming, OVRR believes that public confidence in COVID-19 vaccines would not be served by rushing our review and evaluation of the submitted data. In addition, Dr. Krause and I pointed out the very important regulatory issues that still need to be settled by the time we take action on this BLA—including the pediatric plan — which is becoming increasingly complex in light of increasing evidence of association of this vaccine and development of myocarditis (especially in young males, but also ages included in the BLA indication). This also impacts the finalization of post-marketing requirements and post-marketing commitments. In addition, there are pending information requests to the sponsor, and there will likely be additional information requests based on ongoing review of the data, and the timing of the sponsor response is beyond CBER control.

I reiterated during our meeting that OVRR is targeting September 15, 2021, as the date we will be taking regulatory action, which is less than 4 months from the date the last section of the BLA was submitted. Thus, we will be reviewing this complex BLA with a large amount of data, in a third of the time typically allowed for a BLA standard application and in less than half the time allocated for a priority review application. In response to your questions, I described OVRR's BLA review assignment processes. I emphasized that for this particular BLA, we assigned two experienced medical officers to this file who are working closely with the data analytics team in CDER-OCS and three statisticians from CBER/OBE who are supporting these review efforts. I did not emphasize this during our meeting, but you should also know that our typical review process includes frequent formal and informal communications with managers at all levels and other OVRR experts not directly assigned to the review team. I reiterated that adding staff to this review at this advanced stage would likely slow down the review due to the need to bring new people up to speed. You inquired whether we need additional help and also asked about the expertise of MOs assigned to this file noting that there would be staff in FDA, e.g., pediatric cardiologist that could assist in the review. You expressed concern about the rising COVID-cases in the US and globally, largely caused by the Delta variant and stated your opinion that, absent a license, states cannot require mandatory vaccination and that people hesitant to get an EUA authorized vaccine would be more inclined to get immunized when the product is licensed. You emphasized your interest in licensing this vaccine as soon as possible—a goal that we agree with. We too are concerned about the rising COVID-19 cases in the US, however, our concern is that a review that is hyper-accelerated beyond the already very rapid September 15 target date and as a consequence, may be less thorough than our typical review seems more likely to undermine confidence in the vaccine (and, indeed, in FDA's credibility) than to increase it.

You informed us of your decision that OVRR management and oversight of the BLA review will be delegated to Dr. Marks who will provide you with weekly updates on the review process and ensure that due diligence is exercised while I am away (b)(6). You also informed me that Dr. Krause will not be involved in the BLA oversight as he will be overseeing other regulatory and programmatic programs in OVRR. I expressed my disagreement with these decisions because standard procedures are for the deputy Office Director to assume an Acting Role when the Office Director is out of the Office. I note that Dr. Krause is a recognized expert in vaccine regulation, development and very familiar with the scientific and clinical issues presented by this specific vaccine product and that the review team relies on his expertise and guidance.

I would also like to emphasize OVRR staff's dedication and experience in promoting public health by making safe and effective vaccines available for use in the United States. Since I believe we all agree in the importance both of a rapid decision and a thorough scientific and credible review, Dr. Krause and the OVRR staff will stand ready to assist in any way possible to achieve both of these goals. Please confirm that this summary reflects your recollection of this meeting. If it does not, I would appreciate your letting me know any specific areas where your recollection is different.

Thank you,
Marion

Marion F. Gruber, Ph.D

Director

Office of Vaccines Research & Review
Center for Biologics Evaluation & Research
Food & Drug Administration, DHHS
10903 New Hampshire Ave.
Building 71, Rm. 3230
Silver Spring, Maryland 20993

Tel.: (301) 796 1856

Email: marion.gruber@fda.hhs.gov



From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 7/21/2021 2:25:03 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Gruber, Marion [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=019cd2669c7048f7a116d72b7682de44-gruber]
CC: Krause, Philip [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=00c6330fea0042fdb5571c3fdef792ed-krause]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: Your email on Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Marion,

I don't have much to add to Janet's response below, except to echo her gratitude for all of your work and to say that I remain absolutely committed to ensuring that we maintain our high quality standards in any work undertaken to further expedite the BLA review.

Thank you again.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Wednesday, July 21, 2021 2:09 PM
To: Gruber, Marion <Marion.Gruber@fda.hhs.gov>
Cc: Krause, Philip <Philip.Krause@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: Your email on Review of Pfizer/BioNTech's BLA for Comirnaty, COVID-19 mRNA vaccine - Summary of meeting dated July 19 2021 - 8:30 am

Dear Marion,

Thank you so much for your email. I appreciate you taking the time to speak on Monday, and appreciate you summarizing our conversation.

To begin with, let me express my sincere thanks for your leadership and for the hard work of the Office of Vaccines over the past year and half. Your efforts have made a tremendous difference in combating this pandemic.

It's clear that we are all in agreement about the public need to license the vaccine as soon as possible. This is a once in a lifetime public health crisis and probably the most important application we will all be involved in. With this public health imperative in mind, as well as the intensifying problem of vaccine hesitancy, we all also agree about the importance of not only reviewing this BLA as efficiently as possible, but also ensuring that it is done thoroughly and in keeping with FDA's high standards that protect and promote the public health. With respect to the specific timeline for completion that you propose, I do not have enough information to venture an opinion. I have asked Peter to become familiar with the details of the various elements of the review process and to work with the team to identify potential efficiencies, which they can report back to me during status updates. I also reiterate my offer to provide any resources that the Agency has to assist in components of the review.

Finally, Marion, I offer you and your family my best wishes.

Janet

From: Hussain, Sana [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=5EE10CDD4E6148579481016D45303CAD-SANA.HUSSAI]
Sent: 8/21/2021 11:23:49 AM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
CC: Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]
Subject: follow-up on Fact Sheet and VIS
Location: Microsoft Teams Meeting
Start: 8/21/2021 12:00:00 PM
End: 8/21/2021 12:30:00 PM
Show Time As: Tentative

Required Attendees: Raza, Mark; Tierney, Julia
Optional Attendees: Edmonds, Amanda

Hi all,

We thought it might make sense to have a quick chat about this if you're available.

Mark and Amanda, I am including you both in case one of you can attend. Happy to change the time if this does not work.

Apologies in advance for scheduling a Saturday meeting.

Thanks,

Sana

Microsoft Teams meeting

Join on your computer or mobile app

[Click here to join the meeting](#)

Or call in (audio only)

(b)(6)

United States, Washington DC

Phone Conference ID: (b)(6)

[Find a local number](#) | [Reset PIN](#)

[Learn More](#) | [Meeting options](#)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Saturday, August 21, 2021 9:07 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Saturday, August 21, 2021 9:03 AM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:46 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

From my understanding thi

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:45 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Yes, that section.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Saturday, August 21, 2021 8:37 AM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter

<Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

I think it is, Mark.

(b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:34 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Sorry – related issue

(b)(5)

(b)(5)

I think it is but am not sure.

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Saturday, August 21, 2021 8:23 AM

To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

(b)(5)

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:39 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:42 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Friday, August 20, 2021 6:36 PM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Dear Amanda,

We'll work through this. We will just have to find something practical to implement, given this is the worst pandemic in a the century.

Best Regards,
Peter

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Sent: Friday, August 20, 2021 6:08 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Same here (b)(5)

(b)(5)

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:59 PM
To: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Sana (b)(5)

(b)(5)

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>
Sent: Friday, August 20, 2021 4:38 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>
Cc: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: FW: follow-up on Fact Sheet and VIS

Hi Mark,

We were hoping you could help us with the question we posed to Amanda below re (b)(5)

Any insight would be greatly appreciated.

Sana

From: Hussain, Sana
Sent: Friday, August 20, 2021 2:59 PM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: RE: follow-up on Fact Sheet and VIS

Hi Amanda,

I know we're still waiting on the okay from CDC, but OVRP had one question as they were reviewing the language in the FS (which they had some clarifying edits, but substantively it remains the same). They are curious re (b)(5)

(b)(5)

(b)(5)

I think there was some confusion and any insight that you have would be greatly appreciated.

Sorry for the trouble (and I do hope (b)(6) is going okay).

Sana

From: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:02 AM

To: Malone, Kevin M (CDC) <kmm2@cdc.gov>

Cc: Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>; Thombley, Melisa L (CDC) <fsy1@cdc.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Subject: FW: follow-up on Fact Sheet and VIS

Kevin, as discussed, here is a

(b)(5)

(b)(5)

Please copy Mark and Sana on any reply.

Thanks,
Amanda

From: Hussain, Sana <Sana.Hussain@fda.hhs.gov>

Sent: Friday, August 20, 2021 9:00 AM

To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Raza, Mark <Mark.Raza@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: RE: follow-up on Fact Sheet and VIS

Thanks so much again for all your help Amanda. Attached is a clean Fact Sheet with the footnote incorporated for where we use the phrase (b)(5) for you to forward to CDC.

I hope you enjoy (b)(6)

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/23/2021 1:30:59 PM
To: Raza, Mark [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5811a7d72ee34aa78ff3c8ccb59f92ee-MRaza]; Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]; Beers, Donald [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d079bf15a01744bd94687d6718ca4c42-Donald.Beer]; Barclay, Lisa (OS) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=18c6508b15a249799140fcd8d9ddc1ac-HHS-Lisa.Ba]
Subject: RE: revised language

Thank [redacted (b)(5)] Don/Amanda,
appreciate your quick review

From: Raza, Mark <Mark.Raza@fda.hhs.gov>
Sent: Monday, August 23, 2021 1:27 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>
Subject: RE: revised language

[redacted (b)(5)]

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Monday, August 23, 2021 1:19 PM
To: Raza, Mark <Mark.Raza@fda.hhs.gov>; Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>; Beers, Donald <Donald.Beers@fda.hhs.gov>; Barclay, Lisa (OS) <Lisa.Barclay@hhs.gov>
Subject: revised language

CBER can live with this – thoughts? Happy to put on a call if we need to talk:

[redacted (b)(5)]

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)

(b)(6) (cell)
Julia.Tierney@fda.hhs.gov



From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/23/2021 5:21:20 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf
Attachments: Sen Johnson Response Draft 082321 500pm.docx

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:17 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits looks reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:25 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi

<Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:09 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could (b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like (b)(5)
(b)(5)
(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,

Peter

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To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

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From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
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Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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Dr. Woodcock,

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Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

FDA-2021-5574-00000239

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/22/2021 11:53:34 AM
To: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]
Subject: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjt.docx
Attachments: Pfizer COVID-19 vaccine Fact sheet for Recipients - (08.21) KMM 082121_ap_dd (002) (002)_sfhjt.docx

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/22/2021 10:23:39 PM
To: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

I think JW just [redacted (b)(5)] and I don't have time to give a solid review, I'm sure it's fine.

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:23 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

That assumes OC and Dr. Woodcock don't have changes they would like to see. If she/you do, we would incorporate those ahead of moving it to OCC.

From: Tantillo, Andrew
Sent: Sunday, August 22, 2021 10:21 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Yes I think after any language is added from others (or even if new language is not added), we need OCC to review. We'll make sure they understand the timeline.

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:19 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks! Does OCC or OGC need to review?

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 10:18 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

I circulated the draft for review to ASL, CDC, and NIH at 4:30, letting them know we'd like to issue tomorrow. I will follow up again in the AM

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:28 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

One of us will loop back ASAP. (For what it's worth [redacted (b)(5)])

[redacted (b)(5)]

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From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 8:53:22 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Moving Janet and Peter to bcc to spare your inbox and will loop back once it moves along. What else needs to happen for this to go out tomorrow?

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 6:33 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andi,

Thanks so much. There is some intentional repetition, as we provided a half page or so of summary at the beginning regarding the key findings from VAERS and then go into the details of how we came to those conclusions.

Thanks so much again for taking the time on a Sunday evening.

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>
Sent: Sunday, August 22, 2021 6:28 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

I'm reviewing on my phone now but will note that some information appears to be repeated. In general, however, agree with this approach as well as the urgency.

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From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26:07 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since [REDACTED] jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:09 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
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Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could

(b)(5)

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Dear Janet,

We absolutely can – and that’s a great addition – a sentence like:

(b)(5)

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(b)(5)

Please see the attached updated version.

Best Regards,
Peter

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FDA-2021-5574-00000244

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U.S. Senator, Wisconsin.

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Sent: 8/23/2021 3:34:01 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056a cec4bc98fdb07bb0548dc86-Paul.Aguila]
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:25:42 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
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Please don't respond, looping in Andi for routing/response.

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Sent: Sunday, August 22, 2021 1:59 PM

To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

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To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Michael Livingston (b)(6)
Sent: 8/24/2021 2:01:52 PM
To: McNeill, Lorrie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=77b0b352c9c24851bf0c7330f53e00d9-McNeill]; Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: [EXTERNAL] Covid question

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Hey Lorrie,

Thank you for the reply and the links.

I will read them most diligently. I am not opposed to vaccine, just concerned that this is a political football.

I will share my finding with ownership and we shall move on from there.

Thanks to both you and Dir Woodcock for such timely responses.

Have a terrific day,
Michael Livingston

From: McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Sent: Tuesday, August 24, 2021 1:10 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Michael Livingston (b)(6)
Subject: RE: [EXTERNAL] Covid question

Thank you, Dr. Woodcock.

Dear Mr. Livingston – I want to assure you that FDA staff conducted a very careful and thorough review of the data and information submitted in the Biologics License Application (BLA) for Comirnaty. We have posted our [Summary Basis of Regulatory Action](#) on our web site, which provides an overview of our evaluation of the application. In particular, please see the evaluation of the clinical data, which begins on page 15 of the document.

We are committed to being as transparent as possible with regard to all vaccines, including the COVID-19 vaccines. We will be posting additional review documents from the specific review disciplines on our web site. You'll be able to find these documents, once available, on the [Comirnaty product page](#) under "Supporting Documents."

If you're interested in reading further, you might be interested in the [Decision Memorandum](#) posted on the web at the time FDA authorized the Pfizer-BioNTech COVID-19 Vaccine for emergency use in December 2020. An additional [Decision Memorandum](#) was posted when the agency extended the authorization to include adolescents 12 through 15 years of age in May, and [again earlier this month](#) with the authorization of an additional dose for certain immunocompromised individuals.

I hope this information is helpful. If you have additional questions, please don't hesitate to contact me directly.

Best regards –

Lorrie

Lorrie H. McNeill

Director

Office of Communication, Outreach and Development
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration
lorrie.mcneill@fda.hhs.gov



From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Tuesday, August 24, 2021 10:56 AM
To: Michael Livingston; (b)(6); McNeill, Lorrie <Lorrie.McNeill@fda.hhs.gov>
Subject: RE: [EXTERNAL] Covid question

I'm connecting you to Ms. McNeill, who can give you the link to posted documents. Janet Woodcock

From: Michael Livingston; (b)(6)
Sent: Tuesday, August 24, 2021 10:52 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: [EXTERNAL] Covid question

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Hello, Dir Woodcock,

How do we as citizens know that the approval of the Covid-19 vaccine is not a political pressure move?
Where are the proofs for layman to view and see how and why it was approved.
I believe and correct me if I am wrong that the mumps vaccine took 4 years to get approved and that was the fastest vaccine to get approved to date.
How is it that this one is approved in under two years?

This is from someone who has had Covid back in April of 2020, tested positive for antibodies in late April of 2021 and I know I was around others that in fact did have covid as I worked with them.

I must be an enigma because I am not seeing any of what is being said. I just keep hearing it and it has made me skeptical beyond belief.

Let me know everything that lead up to the approval and where one can read about the process.

Thanks you and have a terrific day,
Michael Livingston

(b)(6)

This communication is from a subrogation representative and is an attempt to recover a claim, any information obtained will be used for that purpose. This message is intended only for the use of the individual or entity to which it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of the message is not the intended recipient, or the employee or agent responsible for delivering the message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by telephone at **(b)(6)** and destroy this message.

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From: Tantillo, Andrew [/O=EXCHANGELABS/O U=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]
Sent: 8/23/2021 6:00:01 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johns on to NIH CDC FDA.pdf

Thank you!

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Very clear letter. Thanks very much Peter and CBER! Jakea or Frank, this can be signed. jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:44 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Please see the attached clean copy for your review. I removed three paragraphs toward the end that were no longer relevant. Thanks.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:24 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Look I'll await CBER's comments since I did not author this. Happy to look at quickly then. jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:17 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits look reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Monday, August 23, 2021 3:26 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Monday, August 23, 2021 3:25 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:26 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since: (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:09 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:07 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like

(b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Sunday, August 22, 2021 4:02 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 3:51 PM

To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>

Sent: Sunday, August 22, 2021 2:19 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

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From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in

my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Marks, Peter [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=DFBB2B5BD38445CB9C9ADCA3F72DF53A-MARKSP]
Sent: 7/25/2021 5:31:02 PM
To: Naik, Ramachandra [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=6f65ca32552f4cdab961dae0d4576981-NaikR]
Subject: BLA STN 125742/0 – COMIRNATY (COVID-19 mRNA Vaccine) - Follow-up meeting with Dr. Marks
Location: Zoom; (b)(6)
Start: 7/26/2021 9:30:00 AM
End: 7/26/2021 10:00:00 AM
Show Time As: Busy

Thank you so much!

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

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>

Sent: Friday, July 23, 2021 1:34 PM

To: Naik, Ramachandra; Marks, Peter; Krause, Philip; Fink, Doran; Pratt, Douglas R.; McVittie, Loris; Wollersheim, Susan; Lee, Lucia; Schwartz, Ann T; Allende, Maria; Wang, Xiao; Cheung, Anissa; Wang, Hsiaoling; Yitbarek, Emnet; Garcia, Karla; Choudhary, Anil; Alvarado, Esmeralda; Anderson, Marie; Hulme, Cheryl; Al-Humadi, Nabil; Huang, Lei; Yang, Ye; Tang, Xinyu; Thompson, Deborah; Jones, Kathleen (CBER); Fontan, Laura; Price, Gregory; Wu, Zhongren; Ertel, Donald; Allen, Ekaterina; Zubkova, Iryna; Chun, Haecin; Elekwachi, Oluchi; Stewart, Daphne; Baldwin, Brenda; Smith, Michael (CBER); Gottschalk, Laura; Sutkowski, Elizabeth M.; Prutzman, Kirk C; Peden, Keith; Weir, Jerry P.; Levis, Robin; Overking, Cassandra; Verma, Swati; Pan, Tao; Kenney, James; Shahabuddin, Muhammad; Eichelberger, Maryna; Quander III, Joseph; Eltermann, John; Green, Martin (Dave); Lin, Tsai-Lien; Scott, John; Lee, Shiowjen; Baumblatt, Jane; Niu, Manette; Nair, Narayan; Alimchandani, Meghna; Li, Nicole; Peters, Lori; Renshaw, Carolyn; Cato, Dennis; Mampilly, Carrie; Jones, Dana; Stockbridge, Lisa L; Sausville, Robert; Nelle, Timothy; Malarkey, Mary; Anderson, Steven; Finn, Theresa; Farizo, Karen; Roberts, Jeff; Izurieta, Hector; Cho, David S (CBER); Rouse, David; Devore, Nicolette; Marshall, Valerie; Hess, Maureen; Goud, Ravi; Crim, James

Cc: Gruber, Marion; Witten, Celia (CBER); Walinsky, Sarah; Mendoza, Melissa; Kaur, Simleen; Maloney, Diane

Subject: BLA STN 125742/0 – COMIRNATY (COVID-19 mRNA Vaccine) - Follow-up meeting with Dr. Marks

When: Monday, July 26, 2021 9:30 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Zoom; (b)(6)

This is a follow-up meeting with Dr. Marks to that occurred on Friday, June 23, 2021. Dr. Marks indicated that he will discuss the short term solutions with the review team after he has more chance to read file.

Hi there,

Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap
mobile:
Meeting
URL:
Meeting
ID:
Passcode

(b)(6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 551 285 1373 or +1 669 216 1590 or 833
568 8864 (Toll Free)

Meeting
ID:
Passcode

(b)(6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting
ID:
Passcode:
SIP:
Passcode:

(b)(6)

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 8/23/2021 10:01:53 AM
To: Wu, Huiquan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=37eef3070e3e4b8c8da8b3c5115b1957-WUH]
Subject: RE: Today's approval of the first COVID-19 vaccine

Thanks, and kudos to CBER! jw

From: Wu, Huiquan <Huiquan.Wu@fda.hhs.gov>
Sent: Monday, August 23, 2021 9:57 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: Today's approval of the first COVID-19 vaccine

Dear Dr. Woodcock,

Super 😊

All the best,

Huiquan

From: A Message from the Acting Commissioner <message@fda.hhs.gov>
Sent: Monday, August 23, 2021 9:48 AM
To: FDA-Wide <FDA-Wide@fda.hhs.gov>
Subject: Today's approval of the first COVID-19 vaccine

A Message from the Acting Commissioner



Dear Colleagues,

I'm pleased to let you know that today, the FDA approved the first COVID-19 vaccine. The vaccine has been known as the Pfizer-BioNTech COVID-19 Vaccine, and will now be marketed as Comirnaty, for the prevention of COVID-19 disease in individuals 16 years of age and older. The vaccine also continues to be available under emergency use authorization (EUA), including for individuals 12 through 15 years of age, and for the administration of a third dose in certain immunocompromised individuals.

This is an important next step in our continuing battle against the COVID-19 pandemic, and should give the public even greater confidence that this vaccine meets our rigorous high standards for safety, effectiveness, and manufacturing quality for vaccines in the U.S.

This is precisely how our process is designed to work during public health emergencies. Congress equipped the FDA with certain regulatory pathways, such as the EUA, to facilitate the rapid availability and use of medical countermeasures, including vaccines, which are supported by rigorous, scientific standards. We have now arrived at the next stage of this process, which involves our approval of this company's Biologics License Application (BLA).

I want to thank Dr. Marks and his team in the FDA's Center for Biologics Evaluation and Research who have been working so hard to conduct a timely evaluation of this product without any sacrifice in our scientific standards or the

integrity of the vaccine development process. Your review of hundreds of thousands of pages of data, as well as the analyses you conducted to determine that this vaccine met our standards for safety and effectiveness, should go a long way to instilling confidence in those who have continued to be reluctant to get vaccinated, and move us a step closer to ending this pandemic.

As today's action indicates, we will continue to do everything we can to respond to it and protect the public's health.

I encourage you to take a look at the agency's press release and listen to today's media briefing for more detailed information about the approval:

- [FDA Approves First COVID-19 Vaccine](#)
- The media briefing will be live streamed over the [FDA's YouTube page](#).

Sincerely,
Janet

Janet Woodcock, M.D.
Acting Commissioner of Food and Drugs



From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 8/23/2021 3:25:18 PM
To: Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Great! Thanks. wj

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:25 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
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Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could (b)(5)

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Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like: (b)(5)
(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

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Best Regards,
Peter

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Sent: Sunday, August 22, 2021 2:19 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

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From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM
To: Tierney, Julia; Woodcock, Janet
Cc: Fristedt, Andi
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 2:01 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 1:59 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>
Sent: Sunday, August 22, 2021 1:52 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: Woodcock, Janet [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=7B0453354A9A427DB0A66A86C7A36F3D-JANET.WOODC]
Sent: 8/23/2021 5:59:25 PM
To: Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Most welcome and congrats. But you need a break. This was well done. I believe the team will rally after this effort. (we shall see). J w

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:59 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet

Will: (b)(6) tonight.

Thank you so much for all of your support during this process.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:54 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks Peter I hope you get some rest! jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:44 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

Please see the attached clean copy for your review. I removed three paragraphs toward the end that were no longer relevant. Thanks.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:24 PM

To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Look I'll await CBER's comments since I did not author this. Happy to look at quickly then. jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 5:17 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

The response, with edits from OCC and CDC, is attached. (NIH had no comments.) These edits look reasonable to us, but given the sensitivity of this letter we want to make sure you have the opportunity to review. Commissioner, Dr. Marks, if you are comfortable with the edits, we will clean it up, secure the Commissioner's signature, and send the response. If there are any edits you would like to reject, we can certainly do so.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Andy,

Thanks so much.

Best Regards,
Peter

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Monday, August 23, 2021 3:25 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

An update for the group – OCC has completed review (Dr. Marks, we are checking with CBER on one OCC comment). NIH and CDC advise we should get their clearance this afternoon.

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:26 PM
To: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Agree, especially since (b)(5) jw

From: Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:09 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Since this was addressed to FDA, CDC, and NIH, perhaps I should run this draft by them (and HHS), suggesting this could

(b)(5)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:07 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Janet,

We absolutely can – and that’s a great addition – a sentence like:

(b)(5)

(b)(5)

(b)(5)

Please see the attached updated version.

Best Regards,
Peter

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 4:02 PM
To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

(b)(5)

(b)(5)

jw

From: Marks, Peter <Peter.Marks@fda.hhs.gov>
Sent: Sunday, August 22, 2021 3:51 PM
To: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>
Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear All,

Please see a draft response to the Senator. It would probably be good to treat this like the CP responses and get it out just after the approval (just my two cent opinion).

Best Regards,
Peter

From: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>

Sent: Sunday, August 22, 2021 2:19 PM

To: Marks, Peter <Peter.Marks@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: Re: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Thanks, Peter. Looping Andy to merge chains.

Get [Outlook for iOS](#)

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 2:01 PM

To: Tierney, Julia; Woodcock, Janet

Cc: Fristedt, Andi

Subject: RE: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

We have a ready-baked response for this that can be adapted. Will send that along shortly.

Best Regards,
Peter

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Sent: Sunday, August 22, 2021 2:01 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Please don't respond, looping in Andi for routing/response.

From: Marks, Peter <Peter.Marks@fda.hhs.gov>

Sent: Sunday, August 22, 2021 1:59 PM

To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>

Subject: FW: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

Dear Julie,

FYI.

Best Regards,
Peter

From: Johnson, Ron (Ron Johnson) <Ron_Johnson2@ronjohnson.senate.gov>

Sent: Sunday, August 22, 2021 1:52 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Marks, Peter <Peter.Marks@fda.hhs.gov>

Subject: [EXTERNAL] 2021-08-22 Letter from Senator Johnson to NIH CDC FDA.pdf

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dr. Woodcock,

I have attached a letter I am sending to you, Dr. Collins, and Dr. Walensky regarding your decision not to hold a formal advisory committee meeting prior to your impending decision to grant final approval to Pfizer's Covid-19 vaccine. I believe this is a grave mistake and miscalculation on your part, and I urge you to reconsider your decision. As you can see in the attached letter, I have been closely monitoring many issues that should be considered and publicly disclosed and discussed prior to any final FDA approval. Regardless of your decision, you can be assured that I will continue to monitor vaccine efficacy and safety data and conduct legitimate oversight. Bureaucrats within the agencies may not think they have a duty to be open and transparent with the American public they serve, but I do. I will do everything in my power to hold agency personnel accountable, and also make sure Americans have access to information they have the right to know.

Sincerely,

Ron Johnson
U.S. Senator, Wisconsin.

Sent from my iPad

From: O'Neill, Jeff [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=9A75446CDA1244B3AA59AF3B53CC2D4D-ONEILLJ]
Sent: 8/23/2021 9:12:06 PM
To: Alexander, Uchenna [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=fa1bdd67e5534d77b04e8c8f7b658d75-Uchenna.Ale]
CC: Socgfack, Stephanie N. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ceabeb18deca4a559f0a9bc76d27dfc9-Stephanie.S]; Tantillo, Andrew [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c43045bfeef846fa99daa0c3d4772a1c-Andrew.Tant]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]; Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]; Copeland, Jakea [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=d7fe05ed233c42b68be990b12ae2c8c8-Jakea.Copel]
Subject: Senator Johnson Letter
Attachments: 2021-2740 Sen Johnson Response Draft 082321 500pm_toOESjct.pdf

Hi Uchenna,

Please find attached the signed response to Senator Johnson. I understand you will deliver, but please let us know if we need to do anything.

Thank you,

Jeff

From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 8/24/2021 7:26:16 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Safford, Melissa [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=662886bbfbc7441dae59de74071cec71-Melissa.Saf]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: UPDATE #1: Read Ahead for Tue, August 24, 2021
Attachments: 1000- JW and PM memo -Vaccine.Approval 20210823 .docx; 1100-ASCA for the commissioner 2021-08-24 .pptx; 1345-FDA Scripts - Dr. Woodcock review 082321 OCC cleared.docx

MEETING MATERIALS:

10am Hill Staff Call: FDA's Approval of Comirnaty

Note: Same script used for 8/23 Member call

11am Biweekly CDRH Meeting with the Acting Commissioner

1:45pm Studio Time: Record HHS COVID-19 Vaccine Ads

OEA/OMA READING:

- None

Jakea

From: Copeland, Jakea
Sent: Monday, August 23, 2021 8:30 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Sheehy, Janice <Janice.Sheehy@fda.hhs.gov>; Tierney, Julia (Julia.Tierney@fda.hhs.gov) <Julia.Tierney@fda.hhs.gov>; Safford, Melissa <Melissa.Safford@fda.hhs.gov>; Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Jakea Copeland (Jakea.Copeland@fda.hhs.gov) <Jakea.Copeland@fda.hhs.gov>
Subject: Read Ahead for Tue, August 24, 2021

MEETING MATERIALS:

11am Biweekly CDRH Meeting with the Acting Commissioner

OEA/OMA READING:

- None

Jakea Copeland

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Desk Phone: (301) 796-7050

Email: Jakea.Copeland@fda.hhs.gov



From: Tantillo, Andrew [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=C43045BFEEF846FA99DAA0C3D4772A1C-ANDREW.TANT]
Sent: 8/24/2021 9:17:11 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
CC: McBride, Maren [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=b65d2b38307f4b489e266d2178c46793-Maren.Kahn]; Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]; Walinsky, Sarah [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=97a2ad6b3c4549a78542fce1a086f7ea-Sarah.Walin]; Fristedt, Andi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=8ebcdc6531394636a5afcb391a6c0cc3-Andi.Friste]; Aguilar, Paul [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9f4e6056acec4bc98fdb07bb0548dc86-Paul.Aguila]; Rath, Prakash (FDA) [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=91bc5673db6c416e87a453f8b9527cc0-Prakash.Rat]; Buettner, Alexandria [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f5f2ac69c52d4a5fb1e76816766d8d37-Alexandria.]; Howard, Megan [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=905c2a2efa4c45f1b9f67cbd6fa26326-Megan.Howar]; Horne, Eric [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ca6a8f2cc62c451b92951528e4f1a6dc-Eric.Horne]; Klimczak, Katherine [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=01a6c20534774be590c50f0d455c81de-Katherine.K]
Subject: Script for 10am Hill Call
Attachments: Hill Call Script.docx

Attached is the script for the Hill call this morning. Your portions are identical.

Whereas yesterday's call was targeted to certain Members, this will be for all congressional health staff.

Please let me know if you need anything. I'll meet you in the virtual green room ahead of the call. Thank you.

From: Tantillo, Andrew
Sent: Monday, August 23, 2021 11:45 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Peter Marks <Peter.Marks@fda.hhs.gov>
Cc: Maren McBride <Maren.McBride@fda.hhs.gov>; Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Walinsky, Sarah <Sarah.Walinsky@fda.hhs.gov>; Fristedt, Andi <Andi.Fristedt@fda.hhs.gov>; Aguilar, Paul <Paul.Aguilar@fda.hhs.gov>; Rath, Prakash (FDA) <Prakash.Rath@fda.hhs.gov>; Buettner, Alexandria <Alexandria.Buettner@fda.hhs.gov>; Howard, Megan <Megan.Howard@fda.hhs.gov>; Horne, Eric <Eric.Horne@fda.hhs.gov>; Klimczak, Katherine <Katherine.Klimczak@fda.hhs.gov>
Subject: Memo and Script for 3pm Hill Call

Dr. Woodcock and Dr. Marks – Attached is a background memo and script for the 3:00 call with House and Senate leaders. The run of show will be similar to the media call today. Please let us know if you have any questions or need additional information.

Andrew Tantillo, J.D.
Acting Associate Commissioner for Legislative Affairs
Office of Legislation
U.S. Food and Drug Administration

301-796-8919 M: (b)(6)
andrew.tantillo@fda.hhs.gov



Sent: 8/22/2021 9:44:32 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Caccomo, Stephanie [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=950c32cebc4b4f80b302c50cf31c8524-Stephanie.C]
CC: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]; Felberbaum, Michael [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=4819a643ca2945cdb1a2631b83e69673-Michael.Fel]; Rebello, Heidi [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=2834ce193ca949799ef063e34a2cfa0b-Heidi.Rebel]
Subject: RE: For review, media call script for BLA

This is accurate, included small tweaks:

(b)(5) the vaccine continues to be available under emergency use authorization for individuals 12 through 15 years of age and (b)(5) for certain immunocompromised individuals. (b)(5)
(b)(5) Health care providers can continue to use the vaccine on their shelves
(b)(5)
(b)(5)

(b)(5)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:35 AM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review, media call script for BLA

Not sure if this is correct. Julie, you are most aware of the legal niceties here. See modification below, does it work? jw

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 7:53 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review, media call script for BLA

We're happy to check this line with CBER/OCC, if you feel this simplifies the point:

(b)(5)

the vaccine

continues to be available under emergency use authorization for individuals 12 through 15 years of age and for certain immunocompromised individuals.

(b)(5)

health care providers can continue to use the vaccine on their shelves

(b)(5)

(b)(5)

Stephanie Caccomo

Media Relations Director

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: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Sent: Saturday, August 21, 2021 4:47 PM

To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: RE: For review, media call script for BLA

I know everyone at FDA is not confused about this, but the sentence about "sufficient supply of Com.." will confuse everyone not an FDA-er. It would be OK for me to expand on this and explain it a bit, but as it is I think people will lose their train of thought when I say that! jw

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>

Sent: Saturday, August 21, 2021 4:04 PM

To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>

Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>

Subject: For review, media call script for BLA

Hi Janet-

Attached is the CBER and OCC cleared script for your review for Monday's media call on Comirnaty. Please let us know if you have edits.

Thank you!

Stephanie Caccomo

Media Relations Director

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: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/23/2021 2:30:01 PM
To: Jefferson, Erica [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=0bc0bd0f8766484b803f584eb491ace6-Erica.Jeffe]
Subject: updated QA.docx
Attachments: updated QA.docx

Thanks for taking care of handling and getting updated ASAP. Please let me know once it's up and if you have any questions.

THANK YOU!!

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)

(b)(6) (cell)

Julia.Tierney@fda.hhs.gov



From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/23/2021 5:13:20 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
Subject: Johnson letter
Attachments: Sen Johnson Response Draft 082221.docx

Not sure what it looks like at this point, but this is the draft Peter sent yesterday if you want to review (for ethics?) [REDACTED] (b)(5)

Thanks,
Julie

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
[REDACTED] (b)(6) (cell)
Julia.Tierney@fda.hhs.gov



From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/23/2021 8:33:43 PM
To: Helms Williams, Emily [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=873be46f1b1a4d2b8df3fe67137cbdc8-HELMSWILLIA]
CC: Tobias, Lindsay [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=a4766773c717470bbc55d204b5f067b2-Lindsay.Sto]; O'Neill, Jeff [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=9a75446cda1244b3aa59af3b53cc2d4d-ONEILL]; Socgfack, Stephanie N. [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=ceabeb18deca4a559f0a9bc76d27dfc9-Stephanie.S]
Subject: RE: URGENT - 2021-2740 Sen Johnson Response Draft 082321 500pm_toOES.docx
Attachments: 2021-2740 Sen Johnson Response Draft 082321 500pm_toOESjct.docx

Thanks very much to both you and Jeff for such a quick review. This looks fine, but I would not make one of the changes suggested by Jeff (marked on page 2: (b)(5) With that edit, looks good to be finalized, have JW's signature autopenned, and transmitted.

Thanks,
Julie

From: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:27 PM
To: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Cc: Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>
Subject: FW: URGENT - 2021-2740 Sen Johnson Response Draft 082321 500pm_toOES.docx
Importance: High

Julie, I have reviewed (quickly, since I saw the preview version) and have no edits. To the extent needed, this is cleared for ethics and subject matter. This is ready for your review/clearance for COS.

Thanks,
Emily

From: O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>
Sent: Monday, August 23, 2021 8:18 PM
To: Helms Williams, Emily <Emily.HelmsWilliams@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Tobias, Lindsay <Lindsay.Tobias@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>
Subject: URGENT - 2021-2740 Sen Johnson Response Draft 082321 500pm_toOES.docx
Importance: High

Hi Emily,

Attached is the letter to Senator Johnson that I understand needs to go tonight - I made my minor edits in track changes. Below is the clearance history. Please let me know when this is cleared and I will autopen and return to OL.

Thank you,

Jeff

From: Alexander, Uchenna <Uchenna.Alexander@fda.hhs.gov>

Sent: Monday, August 23, 2021 7:35 PM

To: O'Neill, Jeff <Jeff.ONeill@fda.hhs.gov>; Socgfack, Stephanie N. <Stephanie.Socgfack@fda.hhs.gov>

Cc: Olivarria, Frank <Frank.Olivarria@fda.hhs.gov>; Copeland, Jakea <Jakea.Copeland@fda.hhs.gov>; Tantillo, Andrew <Andrew.Tantillo@fda.hhs.gov>

Subject: RE: letter for immediate signature: 2021-2740 Johnson COVID vaccine

Importance: High

Hi Jeff,

The letter is attached, and the clearance is on the final page, and included below:

(b)(5)

I'm copying Jakea and Frank here, as they were included on a previous email thread.

Thanks,
Uchenna

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/18/2021 1:23:06 PM
To: Hussain, Sana [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=5ee10cdd4e6148579481016d45303cad-Sana.Hussai]
Subject: FW: Rollout Kickoff Mtg.: Potential approval of first COVID-19 vaccine
Location: (b)(6)
Start: 8/19/2021 12:00:00 PM
End: 8/19/2021 12:30:00 PM
Show Time As: Tentative

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

From: Wasserman, Jill <Jill.Wasserman@fda.hhs.gov>

Sent: Wednesday, August 18, 2021 1:22 PM

To: Wasserman, Jill; McNeill, Lorrie; Frantz-Bohn, Susan; Rebello, Heidi; Caccomo, Stephanie; Hunt, Alison; Capobianco, Abigail; Felberbaum, Michael; Hetlage, Daniel; Kimberly, Brad; Thorpe, Valarie; Walsh, Sandy; Staton, Anna; Leggin, Brooke; MacRoberts, Matthew; Mulieri, Chris; Braithwaite, Sonia; Alicea-Rivera, Esteban; Hollis, Nicole; Courtney, Brooke; Mair, Michael; Sanchez-Contreras, Gloria; Nunez, Cariny; Fritsch, Beth F.; Shuman, Aya; Rath, Prakash (FDA); Aguilar, Paul; Horne, Eric; Nguyen, Michael A.; Adams, Michelle; Alexander, Nicholas; Madni, Rubina; Zavagno, Denise; Riley, Karen; Finnen, April

Cc: Tierney, Julia; Walinsky, Sarah; Jefferson, Erica; Strachman-Miller, Jason; Guevara, Bessy

Subject: Rollout Kickoff Mtg.: Potential approval of first COVID-19 vaccine

When: Thursday, August 19, 2021 12:00 PM-12:30 PM (UTC-05:00) Eastern Time (US & Canada).

Where: (b)(6)

Confidential-Internal-Deliberative

I apologize that this meeting is scheduled at noon.

This is a rollout kickoff meeting for the potential approval of Comirnaty for the prevention of COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older. This vaccine is currently available under EUA in individuals 12 years of age and older under the name Pfizer-BioNTech COVID-19 Vaccine.

Please review and edit the  DRAFT COMMS PLAN before we meet and come ready to discuss.

Specific timing of this rollout is unknown.

Rollout Meeting Agenda

- Intro/Roll call (Jill Wasserman, OEA)
- CBER Updates
- Comms Plan Walkthrough (All)
- Questions/Discussion (All)
- Next Steps (Jill Wasserman, OEA)

Feel free to reach out to me if you have any questions.

Best,

Jill Wasserman, MPH
Rollout Coordinator, Office of External Affairs
U.S. Food and Drug Administration
Work Cell: (b)(6)
Jill.Wasserman@fda.hhs.gov



Hi there,

Jill Wasserman is inviting you to a scheduled ZoomGov meeting.

Join Zoom Meeting

One tap US: +16692545252,,1608357381#,,,,*102780# or +16468287666,,1608357381#,,,,*102780#
mobile:

Meeting
URL:
Meeting
ID:
Passcode:

(b)(6)

Join by Telephone

For higher quality, dial a number based on your current location.

Dial:

US: +1 669 254 5252 or +1 646 828 7666 or +1 669 216 1590 or +1 551 285 1373 or 833
568 8864 (Toll Free)

Meeting
ID:
Passcode:

(b)(6)

International numbers

Join from an H.323/SIP room system

H.323:

Meeting

ID:

Passcode:

SIP:

Passcode:

(b)(6)

From: Tierney, Julia [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=1160D300BC4248B790DED292A082E9A8-JULIA.TIERN]
Sent: 8/19/2021 9:37:12 AM
To: Edmonds, Amanda [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=232186a24a53474298d2760c060a4cc7-Amanda.Edmo]
Subject: RE: latest version of PI
Attachments: STN 125742.0.58_Revised PI_CBER Edits_08.18.2021.docx

Sorry, this is the latest with comments from Pfizer.

From: Tierney, Julia
Sent: Thursday, August 19, 2021 9:20 AM
To: Edmonds, Amanda <Amanda.Edmonds@fda.hhs.gov>
Subject: latest version of PI

Here is the latest version. I know it's not the only issue (b)(5)

Julia C. Tierney, JD (she/her)
Acting Chief of Staff

U.S. Food and Drug Administration
(301) 796-8602 (office) (forwarded)
(b)(6) (cell)
Julia.Tierney@fda.hhs.gov



From: PMDA-Update [pmda_update@pmda.go.jp]
Sent: 6/17/2021 3:57:02 AM
Subject: [EXTERNAL] Four new review reports available [Comirnaty], [Opdivo], [Orkedia] and [Velexbru]

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear colleagues,

PMDA Update* is delighted to inform you that four new review reports are now available in English. Please refer to the information below for detail.

*PMDA Update is free e-mail service that provides news and information on PMDA's international activities from PMDA Office of International Programs.

Approval Category:

Drug, special approval for emergency

Brand Name:

Comirnaty Intramuscular Injection

Non-proprietary Name:

Coronavirus Modified Uridine RNA Vaccine (SARS-CoV-2)
(Active ingredient: Tozinameran)

Applicant:

Pfizer Japan Inc.

Approval Date:

February 14, 2021

Indication:

Prevention of disease caused by SARS-CoV-2 infection (COVID-19)

Dosage and Administration:

The product is diluted with 1.8 mL of physiological saline (Japanese Pharmacopoeia grade), and 2 doses (0.3 mL each) are injected intramuscularly, usually 3 weeks apart.

Review Reports for Approved Drugs:

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html>

Report on Special Approval for Emergency for Comirnaty (English):

<https://www.pmda.go.jp/files/000241164.pdf>

Report on Special Approval for Emergency for Comirnaty (Japanese):

https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_A100_5.pdf

Approval Category:

Drug, partial change approval

Brand Name:

Opdivo Intravenous Infusion 20 mg

Opdivo Intravenous Infusion 100 mg

Opdivo Intravenous Infusion 240 mg

Non-proprietary Name:

Nivolumab (Genetical Recombination)

Applicant:

Ono Pharmaceutical Co., Ltd.

Approval Date:

February 21, 2020

Indication:

1. Treatment of malignant melanoma
 2. Treatment of unresectable, advanced or recurrent non-small cell lung cancer
 3. Treatment of unresectable or metastatic renal cell carcinoma
 4. Treatment of relapsed or refractory classical Hodgkin lymphoma
 5. Treatment of recurrent or metastatic head and neck cancer
 6. Treatment of unresectable, advanced or recurrent gastric cancer that has progressed after cancer chemotherapy
 7. Treatment of unresectable, advanced or recurrent malignant pleural mesothelioma that has progressed after cancer chemotherapy
 8. Treatment of unresectable, advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy
 9. Treatment of unresectable, advanced or recurrent esophageal cancer that has progressed after cancer chemotherapy
- (Underline denotes additions.)

Dosage and Administration:

1. Treatment of malignant melanoma
The usual adult dosage of nivolumab (genetical recombination) is 240 mg administered as an intravenous infusion every 2 weeks. For the adjuvant therapy of malignant melanoma, the maximum duration of treatment is 12 months.
In combination therapy with ipilimumab (genetical recombination) for unresectable malignant melanoma, the usual adult dosage of nivolumab (genetical recombination) is 80 mg administered as an intravenous infusion every 3 weeks for 4 doses, followed by 240 mg as an intravenous infusion every 2 weeks.
2. Treatment of unresectable or metastatic renal cell carcinoma
The usual adult dosage of nivolumab (genetical recombination) is 240 mg administered as an intravenous infusion every 2 weeks.
When administered in combination with ipilimumab (genetical recombination) to chemotherapy-naïve patients with unresectable or metastatic renal cell carcinoma, the usual adult dosage of nivolumab (genetical recombination) is 240 mg administered as an intravenous infusion every 3 weeks for 4 doses, followed by 240 mg as an intravenous infusion every 2 weeks.
3. Treatment of unresectable, advanced or recurrent non-small cell lung cancer, relapsed or refractory classical Hodgkin lymphoma, recurrent or metastatic head and neck cancer, unresectable, advanced or recurrent gastric cancer that has progressed after cancer chemotherapy, unresectable, advanced or recurrent malignant pleural mesothelioma that has progressed after cancer chemotherapy, unresectable, advanced or recurrent microsatellite instability-high (MSI-High) colorectal cancer that has progressed after cancer chemotherapy, or unresectable, advanced or recurrent esophageal cancer that has progressed after cancer chemotherapy

The usual adult dosage of nivolumab (genetical recombination) is 240 mg administered as an intravenous infusion every 2 weeks.
(Underline denotes additions.)

Review Reports for Approved Drugs:

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html>

Review Report for Opdivo (English):

<https://www.pmda.go.jp/files/000241165.pdf>

Review Report for Opdivo (Japanese):

https://www.pmda.go.jp/drugs/2020/P20200228001/180188000_22600AMX00768_A100_1.pdf

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Approval Category:

Drug, partial change approval

Brand Name:

Orkedia Tablets 1 mg

Orkedia Tablets 2 mg

Non-proprietary Name:

Evocalcet

Applicant:

Kyowa Kirin Co., Ltd. (formerly Kyowa Hakko Kirin Co., Ltd.)

Approval Date:

December 20, 2019

Indication:

- ◆ Secondary hyperparathyroidism in patients on maintenance dialysis
- ◆ Hypercalcaemia in patients with any of the following conditions:
 - Parathyroid carcinoma
 - Primary hyperparathyroidism unable to be treated by parathyroidectomy or recurrent primary hyperparathyroidism after parathyroidectomy

(Underline denotes additions.)

Dosage and Administration:

Secondary hyperparathyroidism in patients on maintenance dialysis:

The usual starting dosage for adults is 1 mg of evocalcet administered orally once daily. The starting dose may be 2 mg once daily, depending on the patient's condition. The subsequent oral dose is adjusted within the range from 1 to 8 mg once daily while parathyroid hormone (PTH) and serum calcium levels of the patient are closely monitored. The dose may be increased up to 12 mg once daily if the patient has an inadequate response.

Hypercalcaemia in patients with parathyroid carcinoma and hypercalcaemia in patients with primary hyperparathyroidism who are unable to undergo parathyroidectomy or patients with recurrent primary hyperparathyroidism after parathyroidectomy:

The usual starting dosage for adults is 2 mg of evocalcet administered orally once daily. The starting dose may be 2 mg twice daily, depending on the serum calcium level of the patient. The subsequent oral dose is adjusted, depending on the serum calcium level of the patient, and may be increased to a maximum of 6 mg 4 times daily.

(Underline denotes additions.)

Review Reports for Approved Drugs:

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html>

Review Report for Orkedia (English):

<https://www.pmda.go.jp/files/000241166.pdf>

Review Report for Orkedia (Japanese):

https://www.pmda.go.jp/drugs/2019/P20191213001/230124000_23000AMX00465_A100_1.pdf

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Approval Category:

Drug, partial change approval

Brand Name:

Velexbru Tablets 80 mg

Non-proprietary Name:

Tirabrutinib Hydrochloride

Applicant:

Ono Pharmaceutical Co., Ltd.

Approval Date:

August 21, 2020

Indication:

○ Recurrent or refractory primary central nervous system lymphoma
○ Waldenström's macroglobulinemia and lymphoplasmacytic lymphoma
(Underline denotes additions.)

Dosage and Administration:

The usual adult dosage is 480 mg of tirabrutinib administered orally once daily under fasting conditions. The dose may be reduced according to the patient's condition.

(No change)

Review Reports for Approved Drugs:

<https://www.pmda.go.jp/english/review-services/reviews/approved-information/drugs/0001.html>

Review Report for Velexbu (English):

<https://www.pmda.go.jp/files/000241167.pdf>

Review Report for Velexbu (Japanese):

https://www.pmda.go.jp/drugs/2020/P20200811004/180188000_30200AMX00437_A100_1.pdf

https://www.pmda.go.jp/drugs/2020/P20200811004/180188000_30200AMX00437_A101_1.pdf

(Errata sheet)

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Feel free to contact us for further information.

If you do NOT wish to receive this newsletter, please let us know.

Best regards,
PMDA Update

Sent: 8/22/2021 9:59:58 AM
To: Tierney, Julia [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=1160d300bc4248b790ded292a082e9a8-Julia.Tiern]
Subject: RE: For review, media call script for BLA

I like putting all that

From: Tierney, Julia <Julia.Tierney@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:49 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>; Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review, media call script for BLA

This is accurate, included small tweaks:

(b)(5) the vaccine continues to be available under emergency use authorization for individuals 12 through 15 years of age and (b)(5) for certain immunocompromised individuals. (b)(5)

(b)(5) Health care providers can continue to use the vaccine on their shelves

(b)(5)

(b)(5)

(b)(5)

From: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Sunday, August 22, 2021 9:35 AM
To: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review, media call script for BLA

Not sure if this is correct. Julie, you are most aware of the legal niceties here. See modification below, does it work? jw

From: Caccamo, Stephanie <Stephanie.Caccamo@fda.hhs.gov>
Sent: Sunday, August 22, 2021 7:53 AM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review, media call script for BLA

We're happy to check this line with CBER/OCC, if you feel this simplifies the point:

(b)(5) the vaccine continues to be available under emergency use authorization for individuals 12 through 15 years of age and for certain immunocompromised individuals. (b)(5) health care providers can continue to use the vaccine on their shelves. (b)(5) (b)(5)

Stephanie Caccomo
Media Relations Director

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: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:47 PM
To: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: RE: For review, media call script for BLA

I know everyone at FDA is not confused about this, but the sentence about (b)(5) (b)(5) it would be OK for me to expand on this and explain it a bit, but as it is I think people will lose their train of thought when I say that! jw

From: Caccomo, Stephanie <Stephanie.Caccomo@fda.hhs.gov>
Sent: Saturday, August 21, 2021 4:04 PM
To: Woodcock, Janet <Janet.Woodcock@fda.hhs.gov>
Cc: Tierney, Julia <Julia.Tierney@fda.hhs.gov>; Jefferson, Erica <Erica.Jefferson@fda.hhs.gov>; Felberbaum, Michael <Michael.Felberbaum@fda.hhs.gov>; Rebello, Heidi <Heidi.Rebello@fda.hhs.gov>
Subject: For review, media call script for BLA

Hi Janet-

Attached is the CBER and OCC cleared script for your review for Monday's media call on Comirnaty. Please let us know if you have edits.

Thank you!

Stephanie Caccomo
Media Relations Director

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: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 8/24/2021 9:45:45 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: 10 AM Hill Staff Call: FDA's Approval of Comirnaty
Attachments: 1000-JW and PM memo -Vaccine.Approval 20210823 .docx

1-888-947-9968 (b)(6)

Jakea Copeland

Immediate Office, Office of the Commissioner
U.S. Food and Drug Administration
Desk Phone: (301) 796-7050
Email: Jakea.Copeland@fda.hhs.gov



From: Copeland, Jakea [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=D7FE05ED233C42B68BE990B12AE2C8C8-JAKEA.COPEL]
Sent: 7/26/2021 9:13:51 AM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: Sheehy, Janice [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=f45a6c96f5274724a1be5970eb648ff7-JSheehy]; Olivarria, Frank [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=c180721db774423f99990dd86e67057c-Frank.Oliva]
Subject: 9:30 AM: BLA STN 125742/0 – COMIRNATY (COVID-19 mRNA Vaccine) - Follow-up meeting with Dr. Marks

Hi there,

Ramachandra.Naik@fda.hhs.gov is inviting you to a scheduled ZoomGov meeting.

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Jakea Copeland

Immediate Office, Office of the Commissioner

U.S. Food and Drug Administration

Desk Phone: (301) 796-7050

Email: Jakea.Copeland@fda.hhs.gov



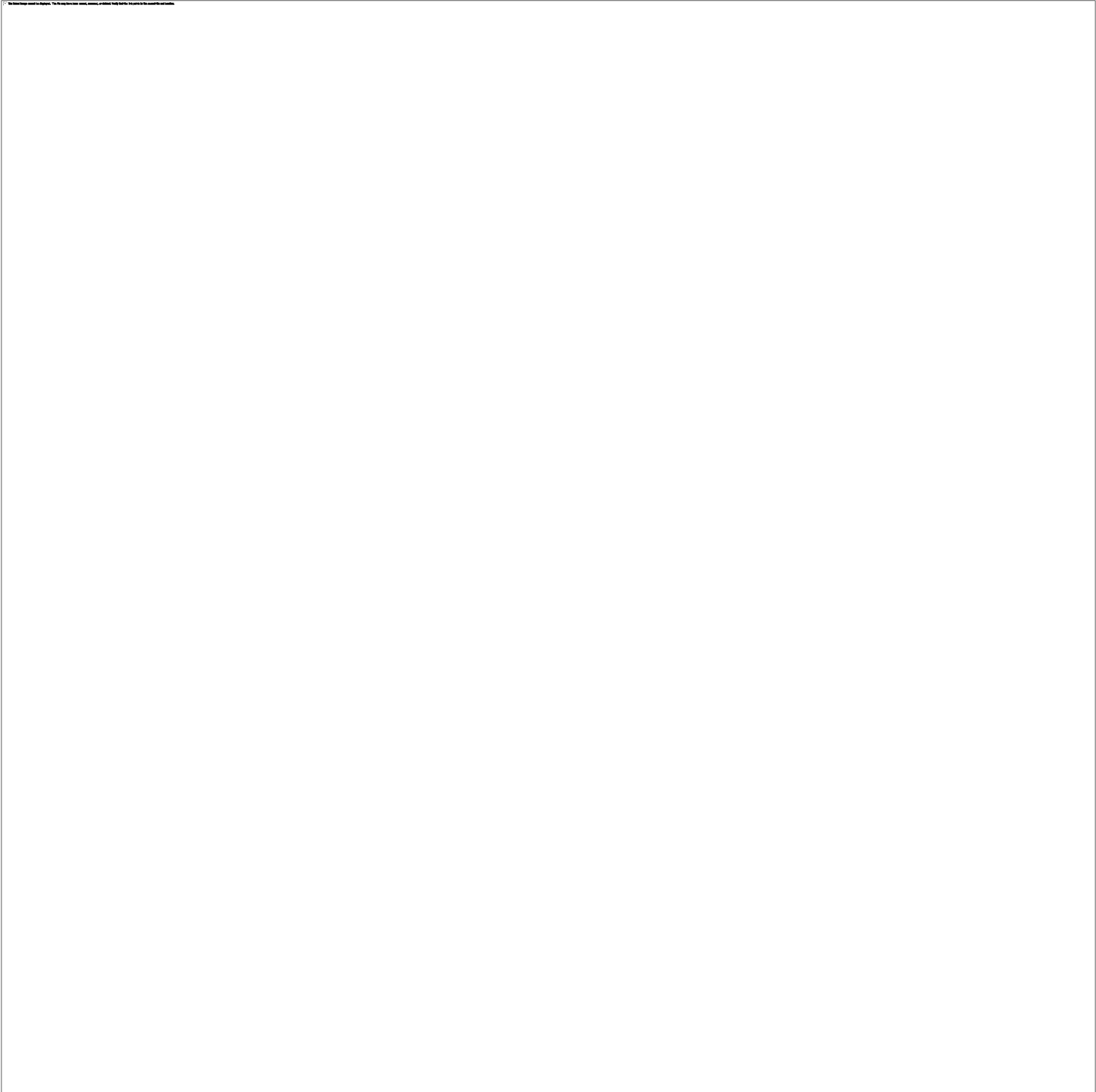
From: Mia Ivy (b)(6)
Sent: 8/16/2021 1:12:11 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]
CC: CDER DRUG INFO [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=82081760a0544b00be5884dfcf1f96cb-DRUGINFO]
Subject: [EXTERNAL] Covid19 Vaccines

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Please do not approve this experimental drug until there has been further studies, testing and better success rate.

I'm providing a link to this information as well.

<https://www.globalresearch.ca/20595-dead-1-9-million-injured-50-serious-reported-european-union-database-adverse-drug-reactions-covid-19-shots/5751904>



20,595 Dead 1.9 Million Injured (50% Serious) Reported in European Union’s Database of Adverse Drug Reactions for COVID-19 Shots

By Brian Shilhavy

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The European Union database of suspected drug reaction reports is [EudraVigilance](#), and they are now reporting 20,595 fatalities, and 1,960,607 injuries, following COVID-19 injections.

A *Health Impact News* subscriber from Europe reminded us that this database maintained at EudraVigilance is only for countries in Europe who are part of the European Union (EU), which comprises 27 countries.

The total number of countries in Europe is much higher, almost twice as many, numbering around 50. (There are some differences of opinion as to which countries are technically part of Europe.)

So as high as these numbers are, they do NOT reflect all of Europe. The actual number in Europe who are reported dead or injured due to COVID-19 shots would be much higher than what we are reporting here.

The EudraVigilance database reports that through July 31, 2021 there are **20,595 deaths and 1,960,607 injuries** reported following injections of four experimental COVID-19 shots:

- [COVID-19 MRNA VACCINE MODERNA \(CX-024414\)](#)
- [COVID-19 MRNA VACCINE PFIZER-BIONTECH](#)
- [COVID-19 VACCINE ASTRAZENECA \(CHADOX1 NCOV-19\)](#)
- [COVID-19 VACCINE JANSSEN \(AD26.COVS.2.S\)](#)

From the total of injuries recorded, half of them (968,870) are **serious** injuries.

*“**Seriousness** provides information on the suspected undesirable effect; it can be classified as ‘serious’ if it corresponds to a medical occurrence that results in **death**, is life-threatening, requires inpatient hospitalisation, results in another medically important condition, or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly/birth defect.”*

A *Health Impact News* subscriber in Europe ran the reports for each of the four COVID-19 shots we are including here. This subscriber has volunteered to do this, and it is a lot of work to tabulate each reaction with injuries and fatalities, since there is no place on the [EudraVigilance](#) system we have found that tabulates all the results.

Since we have started publishing this, others from Europe have also calculated the numbers and confirmed the totals.*

Here is the summary data through July 31, 2021.

Total reactions for the experimental mRNA vaccine Tozinameran (code BNT162b2, Comirnaty) from BioNTech/ Pfizer: 9,868 deaths and 767,225 injuries to 31/07/2021

- 21,004 Blood and lymphatic system disorders **incl. 126 deaths**
- 19,717 Cardiac disorders **incl. 1,489 deaths**
- 177 Congenital, familial and genetic disorders **incl. 14 deaths**
- 9,913 Ear and labyrinth disorders **incl. 8 deaths**
- 471 Endocrine disorders **incl. 3 deaths**
- 11,693 Eye disorders **incl. 21 deaths**
- 69,612 Gastrointestinal disorders **incl. 431 deaths**
- 205,214 General disorders and administration site conditions **incl. 2,832 deaths**
- 779 Hepatobiliary disorders **incl. 46 deaths**
- 8,405 Immune system disorders **incl. 53 deaths**
- 24,114 Infections and infestations **incl. 941 deaths**
- 9,314 Injury, poisoning and procedural complications **incl. 146 deaths**
- 19,170 Investigations **incl. 323 deaths**
- 5,675 Metabolism and nutrition disorders **incl. 178 deaths**
- 104,915 Musculoskeletal and connective tissue disorders **incl. 122 deaths**
- 528 Neoplasms benign, malignant and unspecified (incl cysts and polyps) **incl. 43 deaths**
- 137,631 Nervous system disorders **incl. 1,081 deaths**
- 719 Pregnancy, puerperium and perinatal conditions **incl. 24 deaths**
- 140 Product issues **incl. 1 death**
- 13,659 Psychiatric disorders **incl. 130 deaths**
- 2,481 Renal and urinary disorders **incl. 157 deaths**
- 8,028 Reproductive system and breast disorders **incl. 2 deaths**
- 33,642 Respiratory, thoracic and mediastinal disorders **incl. 1,168 deaths**
- 36,970 Skin and subcutaneous tissue disorders **incl. 87 deaths**
- 1,289 Social circumstances **incl. 13 deaths**
- 564 Surgical and medical procedures **incl. 25 deaths**
- 21,401 Vascular disorders **incl. 404 deaths**

Total reactions for the experimental mRNA vaccine mRNA-1273(CX-024414) from Moderna: 5,460 deaths and 212,474 injuries to 31/07/2021

- 3,901 Blood and lymphatic system disorders **incl. 49 deaths**
- 6,139 Cardiac disorders **incl. 599 deaths**

- 86 Congenital, familial and genetic disorders **incl. 3 deaths**
- 2,699 Ear and labyrinth disorders
- 165 Endocrine disorders **incl. 1 death**
- 3,330 Eye disorders **incl. 13 deaths**
- 18,562 Gastrointestinal disorders **incl. 200 deaths**
- 57,313 General disorders and administration site conditions **incl. 2,188 deaths**
- 345 Hepatobiliary disorders **incl. 20 deaths**
- 1,803 Immune system disorders **incl. 9 deaths**
- 6,151 Infections and infestations **incl. 332 deaths**
- 4,652 Injury, poisoning and procedural complications **incl. 102 deaths**
- 4,289 Investigations **incl. 103 deaths**
- 2,105 Metabolism and nutrition disorders **incl. 125 deaths**
- 26,743 Musculoskeletal and connective tissue disorders **incl. 107 deaths**
- 252 Neoplasms benign, malignant and unspecified (incl cysts and polyps) **incl. 27 deaths**
- 38,118 Nervous system disorders **incl. 552 deaths**
- 432 Pregnancy, puerperium and perinatal conditions **incl. 5 deaths**
- 46 Product issues
- 4,224 Psychiatric disorders **incl. 90 deaths**
- 1,306 Renal and urinary disorders **incl. 85 deaths**
- 1,526 Reproductive system and breast disorders **incl. 2 deaths**
- 9,377 Respiratory, thoracic and mediastinal disorders **incl. 521 deaths**
- 11,300 Skin and subcutaneous tissue disorders **incl. 45 deaths**
- 925 Social circumstances **incl. 20 deaths**
- 700 Surgical and medical procedures **incl. 55 deaths**
- 5,985 Vascular disorders **incl. 207 deaths**

Total reactions for the experimental vaccine AZD1222/VAXZEVRIA (CHADOX1 NCOV-19) from Oxford/ AstraZeneca: 4,534 deaths and 923,749 injuries to 31/07/2021

- 10,912 Blood and lymphatic system disorders **incl. 184 deaths**
- 15,131 Cardiac disorders **incl. 523 deaths**
- 132 Congenital familial and genetic disorders **incl. 3 deaths**
- 10,643 Ear and labyrinth disorders
- 415 Endocrine disorders **incl. 3 deaths**
- 16,108 Eye disorders **incl. 18 deaths**
- 91,912 Gastrointestinal disorders **incl. 229 deaths**
- 244,487 General disorders and administration site conditions **incl. 1,128 deaths**
- 729 Hepatobiliary disorders **incl. 41 deaths**
- 3,663 Immune system disorders **incl. 18 deaths**
- 22,077 Infections and infestations **incl. 284 deaths**

- 10,114 Injury poisoning and procedural complications **incl. 119 deaths**
- 20,068 Investigations **incl. 105 deaths**
- 11,087 Metabolism and nutrition disorders **incl. 62 deaths**
- 140,986 Musculoskeletal and connective tissue disorders **incl. 63 deaths**
- 446 Neoplasms benign malignant and unspecified (incl cysts and polyps) **incl. 13 deaths**
- 194,032 Nervous system disorders **incl. 727 deaths**
- 363 Pregnancy puerperium and perinatal conditions **incl. 8 deaths**
- 135 Product issues **incl. 1 death**
- 17,296 Psychiatric disorders **incl. 39 deaths**
- 3,324 Renal and urinary disorders **incl. 40 deaths**
- 11,369 Reproductive system and breast disorders
- 31,980 Respiratory thoracic and mediastinal disorders **incl. 534 deaths**
- 42,437 Skin and subcutaneous tissue disorders **incl. 30 deaths**
- 1,093 Social circumstances **incl. 7 deaths**
- 971 Surgical and medical procedures **incl. 19 deaths**
- 21,839 Vascular disorders **incl. 336 deaths**

Total reactions for the experimental COVID-19 vaccine JANSSEN (AD26.COV2.S) from Johnson & Johnson: 733 deaths and 57,159 injuries to 31/07/2021

- 531 Blood and lymphatic system disorders **incl. 23 deaths**
- 867 Cardiac disorders **incl. 92 deaths**
- 21 Congenital, familial and genetic disorders
- 346 Ear and labyrinth disorders
- 24 Endocrine disorders **incl. 1 death**
- 705 Eye disorders **incl. 3 deaths**
- 5,449 Gastrointestinal disorders **incl. 27 deaths**
- 15,097 General disorders and administration site conditions **incl. 177 deaths**
- 78 Hepatobiliary disorders **incl. 7 deaths**
- 231 Immune system disorders **incl. 5 deaths**
- 915 Infections and infestations **incl. 21 deaths**
- 529 Injury, poisoning and procedural complications **incl. 11 deaths**
- 2,936 Investigations **incl. 51 deaths**
- 305 Metabolism and nutrition disorders **incl. 12 deaths**
- 9,614 Musculoskeletal and connective tissue disorders **incl. 18 deaths**
- 24 Neoplasms benign, malignant and unspecified (incl cysts and polyps) **incl. 2 deaths**
- 12,240 Nervous system disorders **incl. 90 deaths**
- 17 Pregnancy, puerperium and perinatal conditions **incl. 1 death**
- 17 Product issues

- 659 Psychiatric disorders **incl. 8 deaths**
-

From: Kevin Lawrence; (b)(6)
Sent: 8/4/2021 12:44:48 PM
To: Woodcock, Janet [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=7b0453354a9a427db0a66a86c7a36f3d-Janet.Woodc]; Marks, Peter [/o=ExchangeLabs/ou=Exchange Administrative Group (FYDIBOHF23SPDLT)/cn=Recipients/cn=dfbb2b5bd38445cb9c9adca3f72df53a-MarksP]
Subject: [EXTERNAL] FDA approval of Covid-19 vaccines - Significant flaws in the studies.

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The Covid-19 vaccines currently have emergency approval. The FDA is working on standard approval of the Covid-19 vaccines.

My first hope is that everyone working on the approval of the vaccines, from the interns to the directors have read the studies themselves.

I have emailed more than 40 vaccine "experts", including two from the CDC, and only one of those I contacted had actually read the study. These "Experts" were repeating what other experts were saying, and those experts probably had not read the studies.

If you read the studies and have a moderate understanding of statistics or logic, there are a few unanswered questions. To be honest, there appear to be fairly serious flaws, flaws that should have precluded emergency approval in the first place. These flaws definitely should be considered when determining full approval.

If these flaws had been used to reject the emergency approval, then they could have been addressed with additional stage 3 trials. The additional trials could have determined if the vaccine is actually effective and safe. Unfortunately, now that a significant number of people have received the vaccine, it will be impossible to perform adequate studies to determine efficacy and safety in the vaccinated group compared to the control group. Even the original stage 3 trial has been compromised since many of the control group have subsequently been vaccinated.

I am sure that others have found these issues, but I would like to present them.

In Moderna, Pfizer, and J&J studies, they only accepted people who were at high risk of exposure to covid-19 but never had a lab confirmed covid-19 infection. All three studies chose participants from a group that had a high chance of already having a mild or asymptomatic infection. That criterion is reasonable, the problem is that they did not run antibody tests on the participants at the start of the trials. They trusted the antibody test to make an assessment that the vaccine was causing an antibody response. So, the reason for not testing before admitting the participants cannot be that they did not trust the test, and, given the testing is relatively cheap and given how important it should have been to make sure the participants did not already have antibodies, cost also cannot be used to justify the choice. They have no idea how many in the vaccine group or how many in the control group already had immunity to the virus. That is just bad science. Moderna's claim of 40% antibody response to the vaccine could be false due to participants already having antibodies. To compound the problem, after the vaccine was administered, only the vaccinated group was tested for antibodies. In a double-blind study, both the vaccinated group and the control group should have been given antibody tests. How can we know the antibody response and actual efficacy if we do not know how many participants in the vaccine group and in the control group already had antibodies?

All three studies, for some absurd reason, were not designed to determine if the vaccine prevented infections or the spread of the virus. The studies were designed to determine if the vaccine reduced

symptoms. In nursing homes, facilities are required to test their staff and residents every week. Only study participants that complained of symptoms were tested. In a well-designed study, they would have tested everybody every week. Nursing homes were and are required to test their employees and patients every week, why didn't the study have to do the same testing. A vaccine is defined as "a substance used to stimulate the production of antibodies and provide immunity against one or several diseases". How can these be called vaccines if the study was not designed to show they provided "immunity against one or several diseases"?

In each vaccine study, the control group had at least 10 times lower (confirmed) infection rates than the general population, which by itself should have required another phase 3 trial, but the candidates for the study were supposed to be at a higher risk of contracting the virus than the general population. There must have been some other factor that was causing the reduction in infection rates in the control group. If the control group had significantly lower infection rates than the general population, then what ever caused the reduction in control group infections, may have caused a corresponding infection rate reduction in the vaccinated group. What caused the control group to have significantly lower infection rates than the general population? This issue is, at least in part, resolved when we take into account the suspected but unconfirmed cases. When suspected but unconfirmed cases are included, the control group infection rate is higher than the general population infection rate.

The study <https://www.nejm.org/doi/full/10.1056/nejmoa2034577> found:

"There were 8 cases of Covid-19 with onset at least 7 days after the second dose among participants assigned to receive BNT162b2 and 162 cases among those assigned to placebo"

That sounds pretty impressive, 20 times the number of cases in the control group.

But, in another report published on the FDA website <https://www.fda.gov/media/144245/download>, it says the following "Among 3410 total cases of suspected but unconfirmed COVID-19 in the overall study population, 1594 occurred in the vaccine group vs. 1816 in the placebo group. First, if they were suspected of having covid, why were they not tested. There is absolutely no justification for not testing the suspected cases. When you add the "confirmed" cases to the suspected cases, you end up with 1602 in the vaccinated group and 1978 in the control group. That is only a 10-percentage point difference, or instead of a 20 times higher infection rate in the control group, only a .2 higher rate in the control group. This difference is effectively irrelevant. Why would they choose to not test every suspected Covid-19 infection? Given the flaws in testing for previous existing antibodies, and the nearly irrelevant difference in infections, how do we know this vaccine actually provides any reduction in infections?"

The Cancer Center ran an article in September 2020 titled "RNA's role in cancer growth and treatment resistance" [https:// http://www.cancercenter.com/community/blog/2020/09/cancer-and-rna](https://http://www.cancercenter.com/community/blog/2020/09/cancer-and-rna). The article explains that a recent study found that mutations to mRNA or, mRNA linking up at the wrong spot on the nucleotide chain, may significantly reduce the body's ability to fight cancer. Nothing listed in the mRNA Vaccine studies described any controls for making sure the mRNA in the vaccine was not damaged, nor was there any mention of testing how the mRNA was linking up to the nucleotide chain. Cancer is something that can take a decade or more to show up. With only 6 months of studies, what controls, if any, were put in place to determine a possible increase in cancer rates.

Without reasonable answers to the above questions, we cannot know that the vaccine is effective. We cannot know it is safe.

This question is not related to the studies, but more related to the media and "experts" reporting on the vaccines:

There have been a few media reports that attempt to validate the vaccine's effectiveness by pointing to the reduction in infections and deaths that correspond to the first vaccines being administered. The problem is that the sharp drop in infections occurred at or before the first vaccines were administered,

it took until February 10th for 10% of the population to get their first dose, and March 16th for 10% if the people to get their second dose. In December 2020/January 2021, during a time when infections should continue rising and before enough people were vaccinated, something other than vaccines caused the steep reduction. What that was should be very important and should be examined, but that is unlikely since the media is accrediting the reduction to the vaccine.

In addition, there have been multiple media reports with headlines claiming that 90% of hospitalizations were un-vaccinated people. If you look at the data that the media is using to make this claim, you will often see that they are referring to hospitalizations in January or maybe February. This claim is misleading because it took until Mid February for 10% of the population to get their first dose. If less than 10% of the population had been vaccinated, then if the vaccine was 100% effective, 100% of those hospitalized would be un-vaccinated. *** Lies, damned lies, and statistics. ***

This does not prove the vaccine works, it only proves that 10% of the population had been vaccinated and 90% had not.

On the other hand, if, by mid February, less than 10% of the population had been vaccinated and 10% of those hospitalized were vaccinated, then that would tend to indicate the vaccine was/is not working to reduce hospitalization, or covid-19 infections. This data does more to prove that vaccines do not work than prove it does, but since few people really understand statistics, people miss the implications. If the hospitalizations in the vaccinated group were nearly identical to the proportion that had been vaccinated, how can we know the vaccine is actually effective.

On a bright note, according to statistics, getting the vaccine might actually protect you from some other health problems. There have been heart issues, blot clotting issues, and Guillian Barre. Oddly enough, there were 100 cases of Guillian Barre with 12.8 million vaccines doses. The normal chance of getting Guillian Barre is .001714%, while the rate among those who were vaccinated is around .000781. It appears there is a 2.2 times higher instance of Guillian Barre in the general population than among those who have been vaccinated.

Thank you for your time

Kevin Lawrence