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

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