From: Gruber, Marion
To: Fink, Doran; Krause, Philip
Subject: FW: Your Question to Doran
Date: Tuesday, August 17, 2021 8:55:00 PM
Attachments: BLA 125742 Pfizer BioNTech covid clin rev template.docx

FYI

From: Gruber, Marion
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 you 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 OVRR 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 OVRR 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