To: File

From: Julia Tierney, JD, Acting Chief of Staff

Date: July 21, 2021

Re: July 19, 2021 Meeting with CBER regarding Review of Biologics License Application for Pfizer/BioNTech COVID-19 Vaccine

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On July 19, 2021, Dr. Woodcock, Acting Commissioner of Food and Drugs, and I met with Dr. Peter Marks, Director, Center for Biologics Evaluation and Research (CBER), Dr. Marion Gruber, Director, Office of Vaccine Research and Review (OVRR) in CBER, and Dr. Philip Krause, Deputy Director, OVRR/CBER to discuss the process for review of the Biologics License Application (BLA) for the Pfizer/BioNTech COVID-19 Vaccine.

The meeting began with a discussion of the review process for BLAs in CBER in general and with respect to the Pfizer/BioNTech BLA. Dr. Woodcock asked questions about the structure and staffing of the BLA Review Committee, to which Dr. Gruber responded. Dr. Gruber stressed the complexity of the additional data generated after the EUA issuance that were submitted to the underlying IND, including safety data, and the need to have multiple experienced reviewers for disciplines such as medical officers and statisticians. Dr. Gruber referred to a memo she had provided to Dr. Marks regarding the anticipated timeframe to complete review of the BLA by September 15; Dr. Woodcock acknowledged that Dr. Marks had shared the memo. Dr. Gruber stated that she believed OVRR couldn't compress the review further. Dr. Woodcock asked question about any plans to leverage additional resources from other parts of the agency, such as consults from subject matter experts on CDER's computational science team or pediatric cardiologists in CDER and Commissioner's office. Dr. Gruber acknowledged that they had consulted with some staff in CDER, but not done so widely.

Dr. Krause reiterated many of Dr. Gruber's concerns, stressing that if the review is not thorough, it will further undermine vaccine confidence. He also described some of the additional data that had been submitted since issuance of the EUA, as well as other administrative steps that need to occur.

Dr. Woodcock thanked Dr. Gruber and Dr. Krause for their explanation of the issues associated with the BLA review and stressed the public health importance of this review, including the importance of performing a thorough review. She further stated that she is aware that Dr. Gruber has a (b) (6) [redacted] and will be out of the office for several weeks in July and August. Dr. Gruber acknowledged that she would be out of the office during this time and planned for Dr. Krause to be Acting Director of OVRR in her absence. Dr. Gruber raised that there may be political pressure at play.

Dr. Woodcock emphasized that she has not felt any political pressure, but feels the public health imperative associated with completing the review of the BLA and potentially have a licensed vaccine available. To this end, given the importance of this BLA, while Dr. Gruber is out of office, Dr. Woodcock explained, she is assigning Dr. Marks to lead on the Pfizer/BioNTech BLA, and Dr. Krause will be the Acting Director of OVRR and lead on all other files. Dr. Woodcock reiterated the public health need to complete this review. She will hold Dr. Marks accountable for completing the review as quickly as possible, while performing a thorough review that meets FDA's standards. Dr. Woodcock offered all of the resources of the Agency to get this done as timely as possible. Dr. Woodcock asked that Dr. Gruber transfer leadership of the BLA to Dr. Marks over the next week or two.

Dr. Gruber asked if Dr. Woodcock agreed with the target review date of September 15, 2021 and Dr. Woodcock replied that she would like Dr. Marks to review the status of the file and talk to the team to determine if there is a way to move forward more quickly.

Dr. Gruber stated that she has full confidence in the review team moving forward, as well as Dr. Krause's leadership. Dr. Gruber indicated that the processes in place are well established and that her planned leave wouldn't affect that. She acknowledged Dr. Woodcock's decision to assign leadership of the review to Dr. Marks, but did not agree with it.

Dr. Woodcock stated that she had no doubt about the dedication of the review team or the competence of Dr. Krause as a leader. She indicated that, given the public health priority of this application, she wants as many eyes as possible on this application and wants Dr. Marks to lead this review. She will be asking for briefings on the review, including any issues identified such as potential neurological or cardiological side effects. Dr. Woodcock emphasized that she maintains an open door policy.

Dr. Woodcock again reiterated that she would like Dr. Gruber to work very closely with Dr. Marks to make sure he understands who is doing what and if there are potentially rate limiting steps, such as clinical review, that they are identified and addressed.