

## CONCURRENCE PAGE

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**Application #:** STN: BL 125742.0

**Communication Name:** Filing Notification

**Communication ID:** LTR-BLAFILE-02

**Instructions for entering communication into the appropriate regulatory system:**

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**Drafted by:** M. Smith: 5/18/2021, 5/24/2021

**Review History/concurrence:**

R. Naik: 7/7/2021

M. Smith: 7/15/2021

L. Gottschalk: 7/12/2021

K. Prutzman: 7/7/2021

E. Sutkowski: 7/13/2021

D. Dickerson: 7/7/2021

S. Wollershiem: 7/7/21

A. Schwartz: 7/12/21

D. Thompson: 7/12/2021

H. Chun: 7/7/2021

X. Wang: 7/7/2021

A. Cheung: 7/12/2021

N. Al-humadi: 7/12/2021

M. Anderson: 7/8/2021

L. McVittie: 7/13/2021

D. Dickerson: 7/15/2021

**cc:** CBER Electronic Repository

**END OF CONCURRENCE PAGE**

**The letter begins on the next page.**



Our STN: BL 125742/0

**FILING NOTIFICATION**

BioNTech Manufacturing GmbH  
Attention: Elisa Harkins  
Pfizer Inc.  
500 Arcola Road  
Collegetown, PA 19426

July 15, 2021

Dear Ms. Harkins:

Please refer to your Biologics License Application (BLA) submitted and received on May 18, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 mRNA Vaccine.

We also refer to your amendments submitted and received on May 19, 2021 and June 7, 2021.

We have completed our filing review and have determined that your application is sufficiently complete to permit a substantive review. Under 21 CFR 601.2(a), we have filed your application today. The review classification for this application is **Priority**, the review action due date is January 16, 2022. This acknowledgment of filing does not mean that we have issued a license, nor does it represent any evaluation of the adequacy of the data submitted.

However, we plan to act early on this application under an expedited review, provided that no significant application deficiencies or unexpected shifts in work priorities or team staffing prevent an early action.

This application is also subject to the provisions of “the Program” under the Prescription Drug User Fee Act (PDUFA). Refer to <https://www.fda.gov/industry/prescription-drug-user-fee-amendments/pdufa-vi-fiscal-years-2018-2022>.

We are reviewing your application according to the processes described in the guidance for industry and review staff *Good Review Management Principles and Practices for New Drug Applications and Biologics License Applications* at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/good-review-management-principles-and-practices-new-drug-applications-and-biologics-license>. Therefore, we have established internal review timelines as described in the guidance, which includes the timeframes for FDA internal milestone meetings (e.g., filing, planning, mid-cycle, team and wrap-up meetings). We plan to hold our internal mid-cycle review meeting on August 31, 2021. Please be aware that the timelines described in the guidance are flexible and subject to change based on workload and

other potential review issues (e.g., submission of amendments). We will inform you of any necessary information requests or status updates following the milestone meetings or at other times, as needed, during the process. If major deficiencies are not identified during the review, we plan to communicate proposed labeling and, if necessary, any postmarketing requirement/commitment requests by December 17, 2021.

This date conforms to the 21<sup>st</sup> Century Review timeline for your application. If our review continues on an expedited timeline, we may communicate revised dates for labeling and postmarketing requirement/commitment requests.

At this time, we are not planning a discussion of this application at an Advisory Committee meeting.

At this time, we have not identified any potential review issues. Our filing review is only a preliminary review, and deficiencies may be identified during substantive review of your application. Following a review of the application, we shall advise you in writing of any action we have taken and request additional information if needed.

## **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We acknowledge you have addressed PREA for this application.

If you have any questions, please contact the Regulatory Project Managers, CAPT Mike Smith, Ph.D. (email: [Michael.Smith2@fda.hhs.gov](mailto:Michael.Smith2@fda.hhs.gov)) and Laura Gottschalk, Ph.D. (email: [Laura.Gottschalk@fda.hhs.gov](mailto:Laura.Gottschalk@fda.hhs.gov)), at 301-796-2640.

Sincerely,

Loris D. McVittie, Ph.D.  
Deputy Director - Regulatory  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research