**CONCURRENCE PAGE**

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**Application #:** STN: BL 125742/45

**Communication Name: Filing Notification**

**Communication ID:** LTR-BLSFILE-01

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

- Filing Notification (FL)
- No Deficiencies Identified (NDI)

**Milestone Screen Data Check**
Confirm "Filing Action" Close Date

**Drafted by:** Mike Smith 1/31/22

**Review History/concurrence: :**

R. Naik: 2/4/2022
M. Smith: 2/9/2022
L. Gottschalk: 2/4/2022
E. Sutkowski: 2/4/2022
S. Wollershiem: 2/4/2022
X. Wang: 2/4/2022
T. Finn: 2/8/2022
D. Dickerson: 2/7/2022
K. Ravenell: 2/7/2022
K. Prutzman: 2/4/2022
A. Hornatko-Munoz: 2/7/2022
D. Thompson: 2/7/2022
D. Fink: 2/6/2022
K. Farizo: 2/8/2022

**Concurrence:**
Consumer Safety Officer, OVRR/DVRPA, David Dickerson: 02/09/2022

**cc:** CBER Electronic Repository
Office PMR/PMC Coordinator: Helen Gemignani
CBER PMR/PMC Liaison [CBERPMRPMCLiaison@fda.hhs.gov]
PREA Coordinator: Adrienne Hornatko-Munoz

**END OF CONCURRENCE PAGE**
**The letter begins on the next page.**

Our STN: BL 125742/45

**FILING NOTIFICATION**
February 9, 2022

BioNTech Manufacturing GmbH
Attention: Kathleen Collins, MS
Pfizer, Inc.
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Collins:

Please refer to your supplement to your Biologics License Application (BLA) submitted and received on December 16, 2021, under section 351(a) of the Public Health Service Act (PHS Act) for COVID-19 Vaccine, mRNA (COMIRNATY).

We also refer to your amendment submitted and received on February 2, 2022.

We have completed our filing review and have determined that your supplement is sufficiently complete to permit a substantive review. Under 21 CFR 601.2(a), we have filed your supplement today. The review classification for this supplement is **Priority**, the review goal date is June 17, 2022. This acknowledgment of filing does not mean that this supplement has been approved, nor does it represent any evaluation of the adequacy of the data submitted.

We are reviewing your supplement according to the processes described in the guidance for review staff and industry *Good Review Management Principles and Practices for PDUFA Products* 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). 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 May 18, 2022.

We are not currently planning to hold an advisory committee meeting to discuss this supplement.

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 supplement. Following a review of the supplement, 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 supplements 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) and Laura Gottschalk, Ph.D. (email: Laura.Gottschalk@fda.hhs.gov), at 301-796-2640.

Sincerely,

Loris D. Mcvittie -S

Digitally signed by Loris D. Mcvittie -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=13000647 81, cn=Loris D. Mcvittie -S
Date: 2022.02.09 17:00:08 -05'00'

Loris D. McVittie, Ph.D.
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Evaluation and Research