Our STN: BL 125742/45

ACKNOWLEDGEMENT
PRIOR APPROVAL SUPPLEMENT

BioNTech Manufacturing GmbH
Attention: Amit Patel
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

January 5, 2022

Dear Mr. Patel:

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

Reason for the submission: For active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in adolescents 12 through 15 years of age.

Date of Supplement: December 16, 2021

Date of Receipt: December 16, 2021

US License Number: 2229

Your submission is in the form of a "Prior Approval Supplement" (21 CFR 601.12(b)) that requires CBER approval prior to the distribution of product made using the changes.

Please note that you are also responsible for complying with the applicable provisions of sections 402(i) and (j) of the PHS Act (42 U.S.C. §§ 282(i) and (j), amended by Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law No. 110-85, 121 Stat. 904).

All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to either the CBER Document Control Center at https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/regulatory-submissions-electronic-and-paper or the Electronic Submission Gateway at https://www.fda.gov/electronic-submissions-gateway.

Please note that the Electronic Submissions Gateway (ESG) is an Agency-wide solution for accepting electronic regulatory submissions that enables the secure submission of regulatory information for review. Instructions for setting up an ESG account can be found at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm.

CBER strongly encourages the use of secure email. Secure email makes use of encryption during transmission and the messages are decrypted upon receipt using the certificate. To establish secure email, please follow the instructions in SOPP 8119 *Use of Email for Regulatory Communications,* Appendix A available at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm109645.htm.

This acknowledgment does not mean that this supplement has been approved, nor does it represent any evaluation of the adequacy of the data submitted. Following a review of this submission, we will advise you in writing as to what action has been taken and request additional information if needed.

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

Sincerely,

Elizabeth M. Sutkowski -S

Digitally signed by Elizabeth M. Sutkowski -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300076199, cn=Elizabeth M. Sutkowski -S
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Elizabeth M. Sutkowski, Ph.D.
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