U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125742/0 **ACKNOWLEDGEMENT**

BioNTech Manufacturing GmbH
Attention: Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

May 13, 2021

Dear Ms. Harkins:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (PHS Act) for the following biological product:

Our Submission Tracking Number (STN): BL 125742

Name of Biological Product: COVID-19 mRNA Vaccine

Indication: Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 16 years of age and older.

Date of Application: May 6, 2021

Date of Receipt: May 6, 2021

We have received your application submitted under provision (c) of Section 506 of the Federal Food, Drug, and Cosmetic Act (FDCA) (21 U.S.C. 356) for review of an incomplete application for a Fast Track Product. We acknowledge your schedule for submission of the remaining portions of this application. In accordance with this section of the FDCA, our review clock will not start until the date on which you submit the final portion and inform us that your application is complete.

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)), which was 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.

The Center for Biologics Evaluation and Research (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.

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

Sincerely,

Elizabeth M. Sutkowski, Ph.D.
Chief
Regulatory Review Branch 3
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research