Our Reference: IND 19736

GRANT FAST TRACK DESIGNATION
July 7, 2020

BioNTech RNA Pharmaceuticals GmbH
Attention: Ms. Elisa Harkins
Pfizer, Inc.
500 Arcola Road
Collegeville, PA 19426

Dear Ms. Harkins:

Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FDCA) for "Human Coronavirus mRNA Vaccines (SARS-CoV-2 Spike Protein; BNT162a1 (uRNA; variant RBL063.3); BNT162b1 (modRNA; variant RBP020.3); BNT162b2 (modRNA; variant RBP020.2); and BNT162c2 (saRNA; variant RBS004.2)) in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol)."

We also refer to your request for fast track designation submitted and received on May 15, 2020, and amendment 18, submitted and received on June 18, 2020, under section 506(b) of the FDCA. We have reviewed your request and have determined that Human Coronavirus mRNA Vaccines [SARS-CoV-2 Spike Protein; BNT162b1 (modRNA; variant RBP020.3) and BNT162b2 (modRNA; variant RBP020.2)] in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol) for active immunization to prevent COVID-19 disease caused by SARS-CoV-2 in adults 18 years of age and older meet the criteria for fast track designation. Therefore, we are granting your request for fast track designation. Please note that if the drug development program does not continue to meet the criteria for fast track designation, we may rescind the designation.

For further information regarding fast track drug development programs, please refer to the guidance for industry *Expedited Programs for Serious Conditions – Drugs and Biologics* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM358301.pdf.

We remind you that under section 561A(f)(2) of the FDCA, you are required to make your expanded access policy for Human Coronavirus mRNA Vaccines [SARS-CoV-2 Spike Protein; BNT162b1 (modRNA; variant RBP020.3) and BNT162b2 (modRNA; variant RBP020.2)] in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol) publicly available within 15 days of the signature date of this letter. For further information regarding how to make your expanded access policy publicly available, you may visit our expanded access webpage on FDA.gov at https://www.fda.gov/NewsEvents/PublicHealthFocus/ExpandedAccessCompassionateUse/ucm429687.htm.

If you have any questions, please contact the Regulatory Project Manager, Ramachandra Naik, PhD, at Ramachandra.Naik@fda.hhs.gov or 301-796-2640.

Sincerely,

Doran Fink -S

Digitally signed by Doran Fink -S
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