Pfizer Global Regulatory Affairs
Pfizer Inc.
400 Arcola Road Collegeville, PA 19426

Global Product Development

09 July 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

Re: BLA 125742

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Response to FDA's 25 June 2021 Information Request Regarding a Request for the Lot Release Protocol (LRP) Template and for Samples and Reagents

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 18 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age.

On 25 June 2021, the Agency sent an Information Request regarding for the lot release protocol (LRP) template and for samples and reagents. The requested information is provided in Response to 25 June 2021 FDA IR in Module 1.11.1.

The requested samples and reagents were shipped to the following address in four shipments as detailed below:

Emnet Yitbarek
Food and Drug Administration
Center for Biologics Evaluation and Research
Division of Biological Standards and Quality Control
10903 New Hampshire Avenue

WO75, G-650
Silver Spring, MD 20993

- Three drug substance batches, shipped on July 8, 2021

- Three drug product lots, shipped on July 8, 2021

- Drug substance, drug product and lipid reference materials/controls and (b) (4), shipped on July 8, 2021

- Materials for In vitro expression, RT-PCR and ddPCR, shipped on July 7, 2021

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at elisa.harkinstull@pfizer.com.

Sincerely,

Elisa Harkins
Global Regulatory Lead
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.
CC: Michael Smith, Ph.D.
CC: Laura Gottschalk, Ph.D.