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

Global Product Development

18 August 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)

Commitment as Follow-up to Teleconference with FDA on 17 August 2021 Regarding Andover PAI Response

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 13 August 2021, the Agency sent a request for a meeting with DMPQ subject matter experts and the Pfizer Inc. representatives to discuss Pfizer's Response provided via email on 01 August 2021 (formal submission 02 August 2021) to the FDA Form 483 issued to Pfizer's Andover facility on 23 July 2021. On 17 August 2021, the Agency and Pfizer met via teleconference to discuss the 483 Response. The information and commitments the Agency requested of Pfizer during that meeting are provided in Amendment to Andover COVID-19 BLA FDA 483 Response in Module 1.11.1.

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.
CC: John Eltermann, R.Ph.
CC: Kathleen Jones
CC: Christian Lynch