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

Global Product Development

02 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)

Response to U.S. Food and Drug Administration (FDA) FORM FDA 483, Issued on 23 July 2021

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.

Between 19 July 2021 and 23 July 2021, the U.S. FDA conducted a pre-approval inspection of the Pfizer Andover facility located in Andover, Massachusetts. The present submission provides the following in Module 1.11.1:

- Cover Letter for Response to FORM FDA 483
- Response to FORM FDA 483

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