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

Global Product Development

20 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 FDA 20 August 2021 Seventh Round of Comments on the Draft Package Insert for COMIRNATY

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.

The present submission provides responses and updates to the Agency's 20 August 2021 seventh round of requested changes on the draft package insert for COMIRNATY. The updated draft package insert is provided in Module 1.14.1:

- Track change (PDF and Word)
- Annotated (PDF and Word)
- Clean copy (PDF and Word)

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.
Captain Michael Smith, Ph.D.
Laura Gottshalk, Ph.D.