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

Global Product Development

23 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

COMIRNATY (COVID-19 mRNA Vaccine)

Final Labeling Change – BLA Package Insert for COMIRNATY

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) for COMIRNATY (COVID-19 mRNA Vaccine) developed by BioNTech and Pfizer for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age issued on 23 August 2021.

The present submission provides the final clean copy (PDF and Word) of the package insert for COMIRNATY associated with the receipt of the full FDA approval on 23 August 2021, in Module 1.14.2.

The final Structured Product Labeling (SPL) will be provided in the near future.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 214-918-5262 or via e-mail at Amitkumar.Patel@pfizer.com.

Sincerely,

Amit Patel
Director
Global Regulatory Affairs - Vaccines

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