Pfizer Global Regulatory Affairs
Pfizer Inc.
235 East 42nd Street/New York, NY 10017-5755

Global Product Development

02 May 2022

Peter Marks, M.D., Ph.D.
Active Office 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 125742/45

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

Response to FDA 20 April 2022 Information Request

Revised Pharmacovigilance Plan (PVP) Dated 29 April 2022 Version 1.4.1

Dear Dr. Marks,

Reference is made to the Biologics License Application (BLA) 125742 for COMIRNATY (COVID-19 mRNA Vaccine) developed by Pfizer and BioNTech for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age issued on 23 August 2021. Reference is also made to the sBLA to extend licensure of COMIRNATY to adolescents 12 through 15 years of age submitted to BLA 125742 on 16 December 2021.

Additional reference is made to the email correspondence from Captain Michael Smith, Ph.D. (CBER) to Kathleen Collins (Pfizer Inc.) on 20 April 2022 requesting Pfizer/BioNTech to revise the PVP (Version 1.4, dated December 15, 2021) to include both Tris/Sucrose and PBS/Sucrose formulations and submit to CBER by 04 May 2022.

The present submission provides an updated PVP, version 1.4.1 dated 29 April 2022, Clean copy and Track Changes copy which incorporate both Tris/Sucrose and PBS/Sucrose formulations in Module 1.16.1.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at (b) (6) or via e-mail at (b) (6).

Sincerely,

Kathleen Collins
Senior Director
Global Regulatory Affairs

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