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

Global Product Development

04 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 22 April 2022 Information Request (IR) Regarding Study Protocol for Study C4591022 - Postmarketing Commitment (PMC) #10

Dear Dr. Marks,

Reference is made to the Biologics License Application (BLA) 125742 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. 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.

The purpose of this submission is to respond to FDA 22 April 2022 IR received via email from Captain Mike Smith, PhD, (CBER) to Kathleen Collins (Pfizer Inc.) and Gosia Mineo (Pfizer Inc.) regarding a request to revise the study protocol for Study C4591022 entitled "*Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry"* which is a Postmarketing Commitment (PMC) #10 as described in the STN BLA 125742/0 approval letter.

The response to FDA 22 April 2022 IR is provided in Module 1.11.3.

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.