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

Global Product Development

01 March 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 CBER 23 February 2022 Information Request (IR) Regarding Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age

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 CBER's 23 February 2022 IR received via email from Captain Mike Smith, PhD, (CBER) to Kathleen Collins (Pfizer Inc.) regarding the Cumulative Analysis of Post-Authorization Adverse Event Reports in Individuals Aged Between 12 and 15 Year of Age, submitted to BLA 125742/45 on 16 December 2021. The response to CBER's 23 February 2022 comments 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.