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

Global Product Development

15 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)

Request for Comments and Advice – sBLA Booster Dose for Children 12 Through 15 Years of Age

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 EUA (Emergency Use Authorization) 27034 for Pfizer-BioNTech COVID-19 Vaccine re-issued 3 January 2022.

Reference is also made to the email correspondence from Dr. Ramachandra S. Naik, Ph.D., (CBER) to Ms. Elisa Harkins Tull (Pfizer Inc.) on 20 January 2022 citing FDA agreement on the data requirements supporting Pfizer/BioNTech's plan to submit the sBLA to add a booster dose for individuals ≥16 years old with 6 months safety data post-Dose 3.

The purpose of this submission is to submit a Request for Comments and Advice (Module 1.12.4) requesting feedback from FDA on the acceptability of applying for licensure of a booster dose for adolescents 12 through 15 years of age in the same sBLA planned to apply for licensure of a booster dose for individuals 16 years of age and older as a single submission.

Pfizer/BioNTech respectfully request feedback from the Agency regarding the acceptability of the aforementioned proposal by 22 March 2022.

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.