Pfizer Global Regulatory Affairs
Pfizer Inc.
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Global Product Development

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Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Re: BLA 125742/45

COMIRNATY (COVID-19 mRNA Vaccine)

Supplemental Biologics License Application (sBLA) - Adolescents 12 through 15 Years of Age

Request for Priority Review Designation

Dear Dr. Marks,

Reference is made to the Biologics License Application (BLA) 125742 for COMIRNATY (COVID-19 mRNA Vaccine) approved 23 August 2021 for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. The purpose of this sBLA is to extend licensure of COMIRNATY to adolescents 12 through 15 years of age. The proposed indication is active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

BioNTech and Pfizer are requesting Priority Review Designation for this sBLA. It meets the criteria for Priority Review Designation, as outlined in the 2014 *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics* because COMIRNATY prevents a serious and life-threatening condition (COVID-19) and, if approved, would provide significant improvement in safety and effectiveness because there are currently no vaccines licensed for the prevention of COVID-19 in the US for adolescents 12 through 15 years of age. The Request for Priority Review Designation is provided in Module 1.2.

This sBLA is being submitted as a complete application and the table of contents is attached to this cover letter. Any reference not included with this submission is available upon

request. This submission is provided in electronic Common Technical Document (eCTD) format.

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 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.

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