



Global Product Development

02 February 2022

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Re: BLA 125742/45

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

Response to 19 January 2022 Information Request Regarding Datasets for Adolescents 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 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 made to the sBLA submitted on 16 Dec 2021 to extend licensure of COMIRNATY to adolescents 12 through 15 years of age.

The purpose of this submission is to respond to CBER's 19 January 2022 information request received via email from Captain Mike Smith, PhD, (CBER) to Kathleen Collins (Pfizer Inc.) regarding Datasets for Adolescents 12 Through 15 Years of Age. The requested information is provided in the [Response to CBER's 19 January 2022 comments regarding Datasets for Adolescents 12 Through 15 Years of Age](#) 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.