



Global Product Development

26 August 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
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Re: BLA 125742

COMIRNATY (COVID-19 mRNA Vaccine)

Structured Product Labeling (SPL) – BLA Package Insert for COMIRNATY

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) 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 23 August 2021 and 24 August 2021 submissions of the final BLA package Insert for COMIRNATY. The present submission provides the Structured Product Labeling (Module 1.14.2) for the final BLA Package Insert for COMIRNATY.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free.

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.