



Global Product Development

24 August 2021

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Re: BLA 125742

COMIRNATY (COVID-19 mRNA Vaccine)

Final Labeling Change – 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 submission of the final BLA package Insert for COMIRNATY. The present submission provides again the final clean copy ([PDF](#) and [Word](#)) of the package insert for COMIRNATY associated with the receipt of the full FDA approval on 23 August 2021 with the addition only of the license number into the package insert, in Module 1.14.2.

The final Structured Product Labeling (SPL) will be provided in the near future.

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.