Pfizer Global Regulatory Affairs
Pfizer Inc.
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Global Product Development

29 April 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)

Response to FDA Preliminary Requested Changes and Comments on the Package Insert for COMIRNATY in Individuals 12 Years of Age and Older

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.

Reference is made to the email correspondence from Dr. Ram Ramachandra (CBER) to Gosia Mineo (Pfizer Inc.) on 11 April 2022 that updates to the PBS/Sucrose label would apply to the Tris/Sucrose label and submit the labels for Tris/Sucrose formulation to the sBLA, at the stage of final label negotiations using the PBS/Sucrose label

Additional reference is made to the email correspondence from Dr. Laura Gottschalk, Ph.D., (CBER) to Kathleen Collins (Pfizer Inc.) on 20 April 2022 requesting Pfizer/BioNTech to provide a revised package insert for COMIRNATY in individuals 12 years of age and older addressing FDA's comments and suggested edits by 29 April 2022.

The present submission provides a revised package insert in response to FDA's Preliminary requested changes and comments. The revised package inserts are provided in Module 1.14.1:

- Track Change (Word)
- Annotated (PDF)
- Clean copy (PDF and Word)

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.
CC: Meghan MaguireThon, Ph.D.