



Global Product Development

13 May 2022

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Re: BLA 125742/45

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

Response to FDA's 10 May 2022 Information Request Regarding Package Insert (PI) 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.

Additional reference is made to the email correspondence from Captain Mike Smith, Ph.D., (CBER) to Kathleen Collins (Pfizer Inc.) on 10 May 2022 requesting Pfizer/BioNTech to provide additional revisions to the PI for COMIRNATY in individuals ≥ 12 years of age submitted to BLA 125742/45 on 29 April 2022 for PBS/Sucrose and Tris/Sucrose version of the PI by 16 May 2022.

The present submission provides a revised PI for both the PBS/Sucrose and Tris/Sucrose versions in response to FDA's 10 May 2022 request in Module 1.14.1:

PBS/Sucrose USPI:

- Track Change ([Word](#))
- Annotated ([PDF](#))

- Clean copy ([PDF](#) and [Word](#))

Tris/Sucrose USPI:

- 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.