



## Global Product Development

01 July 2022

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**Re: BLA 125742/45**

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

**Revised United States 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  $\geq 16$  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 125742/45 on 16 December 2021.

Additional reference is made to the 29 June 2022 email correspondence from Captain Michael Smith, Ph.D., (CBER) to Gosia Mineo (Pfizer Inc.) requesting Pfizer/BioNTech to make revisions to the USPI for COMIRNATY in individuals  $\geq 12$  years of age with a replacement of the date previously submitted to BLA 125742/45 on 13 May 2022 for the PBS/Sucrose and Tris/Sucrose versions.

The present submission provides the revised PI with a replacement of the date as requested by CBER for both the PBS/Sucrose and Tris/Sucrose versions in Module 1.14.1:

PBS/Sucrose USPI:

- Track Change ([Word](#))

- Annotated ([Word](#))

Tris/Sucrose USPI:

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

Gosia Mineo, MS  
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.