



## Global Product Development

20 August 2021

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**Re: BLA 125742**

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

**Response to FDA 19 August 2021 Sixth Round of Comments on the Draft Package Insert for COMIRNATY**

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 18 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals  $\geq 16$  years of age.

The present submission provides responses and updates to the Agency's 19 August 2021 sixth round of requested changes on the draft package insert for COMIRNATY. The updated draft package insert is provided in Module 1.14.1:

- Track change ([PDF](#) and [Word](#))
- Annotated ([PDF](#) and [Word](#))
- Clean copy ([PDF](#) and [Word](#))

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at [elisa.harkinstull@pfizer.com](mailto:elisa.harkinstull@pfizer.com).

Sincerely,

Elisa Harkins  
Global Regulatory Lead  
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.  
Captain Michael Smith, Ph.D.  
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