



Global Product Development

19 August 2021

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Food and Drug Administration
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Re: BLA 125742

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

Response to FDA 18 August 2021 Fifth 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 ≥ 16 years of age.

The present submission provides responses and updates to the Agency's 18 August 2021 fifth 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.

Sincerely,

Elisa Harkins
Global Regulatory Lead
Global Regulatory Affairs – Vaccines

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