



Global Product Development

16 August 2021

Marion Gruber, Ph.D.
Director
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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 13 August 2021 Information Request

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 19 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 purpose of this submission is to respond to CBER's 13 August 2021 Information Request, received via email from Ramachandra Naik, PhD (CBER). The requests are regarding Safety-related Postmarketing Requirement and Postmarketing Commitment studies. The [Response to FDA 13 August 2021 Information Request](#) is provided in Module 1.11.3.

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.