



Global Product Development

16 July 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

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Re: BLA 125742

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

Response to 6 July 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 the current document is to respond to CBER's 6 July 2021 Information Request to provide a description of the nature of the severe AEs and the AEs which lead to withdrawal from the stable HIV cohort at any time during the study that was provided by Captain Michael Smith, PhD (CBER) to Pfizer via email. The [Response to CBER's 6 July 2021 Information Request](#) regarding datasets 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.