



Global Product Development

2 July 2021

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Re: BLA 125742

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

Response to 25 June 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 29 June 2021 Information Request regarding study BNT162-01 Interim Report 3 (*bnt162-01-interim3-report-body*) that was provided by Captain Michael Smith, PhD (CBER) to Pfizer via email. The [Response to CBER's 25June2021 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.