



## Global Product Development

16 June 2021

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**Re: BLA 125742**

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

**Response to 8 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  $\geq 16$  years of age. Further reference is made to the clinical information request sent via email from Captain Michael Smith on 8 June 2021.

The purpose of the present submission provides the [Response to CBER's 8 June 2021 Information Request](#) 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](mailto:elisa.harkinstull@pfizer.com).

Sincerely,

Elisa Harkins  
Global Regulatory Lead  
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.