



## Global Product Development

12 August 2021

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**Re: BLA 125742**

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

**Response to FDA 09 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  $\geq 16$  years of age.

The purpose of this submission is to respond to CBER's 09 August 2021 Information Request, received via email from Michael Smith, PhD (CBER). The request is regarding sequencing data for the virus related to study C4591001. The [Response to FDA 09 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](mailto:elisa.harkinstull@pfizer.com).

Sincerely,

Elisa Harkins  
Global Regulatory Lead

Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.