



## Global Product Development

09 August 2021

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**Re: BLA 125742**

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

**Response to 22 July 2021 Information Requests**

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 22 July 2021 Information Request to Pfizer, received via email from Laura Gottschalk, PhD (CBER). The present follow up submission provides the safety 508 tables.

The [Response to CBER's 22 July 2021 Information Requests](#) 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

Marion Gruber, Ph.D., Director  
BLA 125742

Page 2 of 2  
09 August 2021

Global Regulatory Lead  
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CC: Ramachandra S. Naik, Ph.D.