



Global Product Development

02 August 2021

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Re: BLA 125742

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

Response to 29 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 this submission is to respond to CBER's 29 July 2021 Information Request to Pfizer, received via email from Laura Gottschalk, PhD (CBER). The requests are for the provision of the analyses presented in Table 7 (page 116) of the Summary of Clinical Safety for the following age groups: 1) 16 through 55 years, 2) 56 years and older of the 6 month CSR for Study C4591001. The [Response to CBER 29 July 2021 Information Request](#) for Study C4591001 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,

Marion Gruber, Ph.D., Director
BLA 125742

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Elisa Harkins
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CC: Ramachandra S. Naik, Ph.D.