



Global Product Development

26 July 2021

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Re: BLA 125742

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

Response to 22 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 22 July 2021 Information Request to Pfizer, received via email from Laura Gottschalk, PhD (CBER). The requests are regarding clinical shell tables for Study C4591001 that correspond to data filed in the BLA, which is in ongoing CBER review. The [Response to CBER 22 July 2021 Information Request](#) Regarding Clinical Shell Tables 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,

Elisa Harkins

Global Regulatory Lead
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.