



Global Product Development

20 August 2021

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Re: BLA 125742

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

Follow-Up Response to FDA 19 August 2021 Information Request

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 18 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.

Reference is also made to the Response to FDA 13 August 2021 and 19 Information Requests. The purpose of this submission is to respond to CBER's 19 August 2021 Information Request, received via email from Captain Michael Smith, PhD (CBER). The request is for clarification of the study completion date and final report submission date for PMC Study C4591014. The [Response to FDA 19 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.

Sincerely,

Elisa Harkins
Global Regulatory Lead
Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.
Captain Michael Smith, Ph.D.
Laura Gottshalk, Ph.D.