



Global Product Development

30 August 2021

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Re: BLA 125742/0

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

Protocol Amendment for Study C4591012 and New Study C4591009 Protocol

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) 125742/0 for COMIRNATY (COVID-19 mRNA Vaccine) developed by BioNTech and Pfizer for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥ 16 years of age issued on 23 August 2021.

Reference is also made to BB-IND 19736 for the COVID-19 Vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the indication of active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The IND was effective on 29 April 2020.

The present submission is to notify CBER that the following Post-Authorization Safety Study (PASS) protocols were submitted to the BB-IND 19736:

- 4) Study **C4591009** entitled, "*A Non-Interventional Post-Approval Safety Study of Pfizer-BioNTech COVID-19 Vaccine in the United States*" initially submitted to the BB-IND 19736 on 30 August 2021 (SN 0469).
- 12) Study **C4591012** entitled, "*Post-Emergency Use Authorization Active Safety Surveillance Study among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine*" initially submitted to the BB-IND 19736 (SN 0195) on 29 January 2021 and the current

Clinical Protocol incorporating the changes of C4591012 Protocol Amendment 1 submitted to the BB-IND 19736 on 30 August 2021 (SN 0469).

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 214-918-5262 or via e-mail at Amitkumar.Patel@pfizer.com.

Sincerely,

Amit Patel
Director
Global Regulatory Affairs - Vaccines

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