Pfizer Global Regulatory Affairs
Pfizer Inc.
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Global Product Development

21 September 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Avenue
WO71, G112
Silver Spring, MD 20993-0002

Re: BLA 125742/13

COMIRNATY (COVID-19 mRNA Vaccine)

BLA Post-marketing Requirement and Post-Marketing Commitment - Notification of Submission of Final C4591007 Substudy Protocols to IND 19736

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) 125742 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 made 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 C4591007 substudy final protocols were submitted to BB-IND 19736 as protocol amendments to meet Post-marketing Commitment 11 (1) and Post-marketing Requirement 8 (2), both listed in the 23 August 2021 BLA STN 125742/0 approval letter:

(1) Study C4591007 entitled, "A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and immunogenicity and Phase 2/3 Placebo Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young

Adults," submitted to the BB-IND 19736 in **protocol amendment 2** on 10 August 2021 (SN 0443)

(2) Substudy C4591007 entitled, "A Phase 1, Open-Label Dose-Finding Study to Evaluate Safety, Tolerability, and immunogenicity and Phase 2/3 Placebo Controlled, Observer-Blinded Safety, Tolerability, and Immunogenicity Study of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Children and Young Adults," submitted to the BB-IND 19736 in **protocol amendment 3** on 14 September 2021 (SN 0487)

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.