Pfizer Global Regulatory Affairs
Pfizer Inc.
400 Arcola Road Collegeville, PA 19426

Global Product Development

23 July 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

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

Response to 15 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 the current document is to respond to CBER's 15 July 2021 Information Request regarding PREA post-marketing commitment goal dates that was provided by Captain Michael Smith, PhD (CBER) to Pfizer via email. The Response to CBER's 15 July 2021 Information Request regarding datasets is provided in Module 1.11.3.

The present submission also provides the amended agreed Pediatric Study Plan (Clean Copy and Track Changes Copy) and Request for Deferral of Pediatric Studies (Clean Copy and Track Changes Copy) as requested by CBER. These documents have been updated to include the addition of study C4591023, a dose-finding safety and effectiveness study in infants less than 6 months of age. They will also be submitted to BB-IND 19736.

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.