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

Global Product Development

05 August 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 22 July 2021 and 03 August Information Requests

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 present follow up submission provides the efficacy 508 tables, while the safety 508 tables will be provided on 13 August 2021. Additional reference is made to CBER's 03 August 2021 Information Request received via email from Michael Smith, PhD (CBER) regarding Subject C4591001 1001 10031167 and SAS programs used to generate efficacy analyses.

The Response to CBER's 22 July 2021 and 03 August 2021 Information Requests 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.