Pfizer Inc
500 Arcola Road
Collegeville, PA 19436

Global Product Development

10 July 2020

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

SN0030

Re: COVID-19 Vaccine (BNT162; PF-07302048) BB-IND 19736

IND Amendment – Clinical: Response to FDA Information Request

Dear Dr. Gruber,

Reference is made to BB-IND 19736 for the COVID-19 Vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the prevention of COVID-19 in adults ≥18 years of age. The IND was effective on April 29, 2020 and Pfizer initiated a Phase 1/2 US clinical study (C4591001) on May 4, 2020.

The purpose of this submission is to provide clinical assays (IgG binding and SARS-CoV-2 neutralizing antibody assays) as requested by CBER on 06 July 2020 in support of the C4591001 Phase 2b/3 study start scheduled for the week of 20 July 2020 (Module 1.11.3 Response to FDA Request for Information).

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 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.