Pfizer Inc
500 Arcola Road
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Global Product Development

25 August 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

SN0068

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

Response to FDA 29 July 2020 Information Request - Clinical Assay Qualification

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 29 April 2020.

Further reference is made to the Qualification Information (assay method/manual and qualification report) for the Luminex Assay for Quantitation of IgG Antibodies and the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay submitted to BB-IND 19736 on 10 July 2020 (SN 0030).

The present submission provides response to CBER's information request received via email on 29 July 2020 regarding clinical assay qualification [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.