Pfizer Inc.
500 Arcola Road
Collegeville, PA 1426

Global Product Development

04 December 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

SN0156

Re: Covid-19 Vaccine (BNT162/PF-07302048) BB-IND 19736

IND Amendment – New Protocol

Dear Dr. Gruber,

Reference is made to BB-IND 19736 for the COVID-9 vaccine (BNT162; PF-07302048), which Pfizer and BioNTech are developing for the prevention of COVID-19 in adults ≥ 16 years of age. The IND was effective on April 29, 2020.

Further reference is made to Pfizer's Clinical Information Amendment which included the validation packages for the two diagnostic assays (Cepheid Xpert Xpress RT-PCR test for the detection of SARS-CoV-2 in nasal swabs and Roche Elecsys Anti-SARS-CoV-2 assay for the evaluation of serostatus to SARS-CoV-2) submitted on 31 July 2020 (SN0049). Subsequently, on 8 August 2020 CBER confirmed via email (communication from FDA Project Manager Ramachandra Naik to Pfizer's Elisa Harkins) that they concur with the use of these assays in study C4591001 but would be requesting additional information and clarification on the interpretation of assay results.

The present submission provides VR-MVP-10074 - Validation Protocol for the SARS-CoV-2 mNeonGreen Virus Microneutralization Assay.

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.