Pfizer Global Regulatory Affairs
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Global Product Development

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Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
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Document Control Center
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

SN 0413

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

IND Amendment – Protocol Amendment for Study C4591001

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 indication of active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The IND was effective on 29 April 2020.

Reference is also made to Study C4591001 protocol entitled, "*A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals*" and the current C4591001 Clinical Protocol incorporating Amendment 16 submitted to the IND on 02 June 2021 (SN 0353).

The present submission provides C4591001 Clinical Protocol Amendment 17 in Module 5.3.5.1, Clean copy and Tracked change copy.

Protocol Amendment 17 includes the following key changes:

- Changed the analysis method for the within-group comparison of seroresponse rates for Phase 3 booster and VOC immunogenicity assessment from the Miettinen and Nurminen method to the adjusted Wald interval to provide tighter CI and higher power for NI in most cases.
- Clarified that any nonstudy coronavirus vaccines are to be recorded at any time they are given during study participation.

- Clarified that participants who are randomized in the C4591031 study should be withdrawn from this study.

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 212-733-2613; via facsimile at 845-474-3500; or via e-mail at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D.
Director
Pfizer Global Regulatory Affairs

CC: Ramachandra S. Naik, Ph.D.
CC: Laura Gottschalk, Ph.D.
CC: Captain Michael Smith, Ph.D.