Pfizer Global Regulatory Affairs
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Global Product Development

07 May 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

SN 0324

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

IND Amendment – Statistical Analysis Plan for Study C4591020

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 ≥16 years of age. The IND was effective on April 29, 2020.

Reference is also made to study C4591020 protocol entitled, "*A Phase 3, Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Lyophilized Formulation of the Vaccine Candidate BNT162b2 Against COVID-19 in Healthy Adults 18 Through 55 Years of Age*" submitted to the IND on 18 February 2021 [SN 0221; (Module 5.3.5.1)].

Enclosed in this submission is the revised Statistical Analysis Plan version 2 for Study C4591020 provided in Module 5.3.5.1, Clean Copy and Track Changes.

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.