Pfizer Global Regulatory Affairs
Pfizer Inc.
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Global Product Development

18 February 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

SN0221

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

CMC Amendment – Briefing Package Type C Written Response Only

IND Amendment –

- **Clinical: New Protocol for Study C4591020**
- **Informed Consent Document for Study C4591020**

Dear Dr. Gruber,

Reference is made to BB-IND 19736 for BioNTech's COVID-19 Vaccine (BNT162; PF-07302048) 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 the Type C Meeting request submitted on 08 February 2021 (SN0206) to discuss new ready-to-use (RTU) and lyophilized formulations of COVID-19 vaccine BNT162b2 / PF-07302048.

Please find enclosed the meeting background materials, consisting of the Briefing Document (Module 1.6.2) to support CBER's feedback to BioNTech/Pfizer Written Response Only (WRO).

Pfizer and BioNTech respectfully request feedback on the new RTU and lyophilized formulations by 5 March 2021.

This submission also provides the following in Module 5.3.5.1:

- 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*"
- The Informed Consent Document for Study C4591020

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.