Pfizer Inc.
235 East 42nd Street
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Global Product Development

29 January 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
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Silver Spring, MD 20993-0002

SN0195

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

IND Amendment – Post-authorization Safety Studies: Study C4591008, C4591011, C4591012 Protocols

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.

The present submission provides the final protocol for the three post-authorization epidemiological safety studies:

- C4591008 entitled, "*HERO Together: A Post-Emergency Use Authorization Observational Cohort Study to Evaluate the Safety of the Pfizer-BioNTech COVID-19 Vaccine in US Healthcare Workers*"
- C4591011 entitled, "*Active Safety Surveillance of the Pfizer-BioNTech COVID-19 Vaccine in the United States Department of Defense Population Following Emergency Use Authorization*"
- C4591012 entitled, "*Post-Emergency Use Authorization Active Surveillance Study among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine*"

Please note, as explained in the Pharmacovigilence Plan, the milestone due dates associated with these reports were contingent upon vaccine availability on 1 December 2020. However, since supply was not available as of 1 December 2020 the interim reports based on a 31

March 2021 have been removed from the protocols. The first interim report will now be the 30 June 2021 report.

These protocols are being submitted to both BB-IND 19736 and EUA 27034 in parallel.

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,

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CC: Ramachandra S. Naik, Ph.D.