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Global Product Development

30 June 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 0386

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

IND Amendment – Non-Interventional Study Interim Report for Study C4591008 and C4591012

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 and the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine issued on 10 May 2021.

Reference is also made to the protocols for the Post-Authorization Safety Studies (PASS) submitted to the IND 19736 (SN 0195) and EUA 27034 on 29 January 2021:

- 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*".
- 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*".

The present submission provides the:

- Non-Interventional Study Interim Report version 1.0 for Study C4591008
- Non-Interventional Study Interim Report version 1.0 for Study C4591012

This is being submitted to both BB-IND 19736 and EUA 27034 in parallel.

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.