Global Regulatory Affairs - Vaccines
Pfizer Inc.
500 Arcola Road
Collegeville, PA 19426-3982

Global Product Development

15 January 2021

Marion Gruber, Ph.D.
Director
Food and Drug Administration
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
c/o Central Document Room
10903 New Hampshire Avenue, WO71-G112
Silver Spring, MD 20993-0002

Re: COVID-19 Vaccine (BNT162/PF-07302048) BB-IND 19736
SN 0184

IND Summary Monthly Safety Report: Reporting Period 01-DEC-2020 – 31-DEC-2020

Dear Dr. Gruber,

The provided report summarizes information associated with the subject IND during the reporting period. Please note that the format of the IND Annual Report for 2020 has been converted from the format described in 21 CFR 312.33 to the Summary Monthly Safety Report (SMSR) format described in *International Conference on Harmonization; Guideline E2C (R2) Periodic benefit-risk evaluation report (PBRER), Step 5, January 2013.*

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 please contact me via phone at 215-280-5503; or via email at Elisa.HarkinsTull@pfizer.com.

Sincerely,

Elisa Harkins
Global Regulatory Lead
Global Regulatory Affairs - Vaccines