Global Regulatory Affairs - Vaccines Pfizer Inc. 235 East 42nd Street New York, NY 10017



Global Product Development

15 June 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

THIS DOCUMENT CONTAINS
CONFIDENTIAL AND/OR TRADE SECRET
INFORMATION THAT IS DISCLOSED
ONLY IN CONNECTION WITH THE
LICENSING AND/OR REGISTRATION OF
PRODUCTS FOR PFIZER INC OR ITS
AFFILIATED COMPANIES. THIS
DOCUMENT SHOULD NOT BE DISCLOSED
OR USED, IN WHOLE OR IN PART, FOR
ANY OTHER PURPOSE WITHOUT THE
PRIOR WRITTEN CONSENT OF PFIZER
INC

Re: COVID-19 Vaccine (BNT162/PF-07302048) BB-IND 19736 eCTD Sequence 0366 Serial No. 0365

IND Summary Monthly Safety Report: Reporting Period 30-APR-2021 – 31-MAY-2021

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 2021 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.

BB-IND 19736 15 June 2021

Should you have any questions regarding this submission please contact me via phone at 212-733-2613; or via email at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D. Director Pfizer Global Regulatory Affairs