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



Global Product Development

14 May 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 0335 Serial No. 0334

IND Summary Monthly Safety Report: Reporting Period 01-APR-2021 – 29-APR-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.

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