Pfizer Global Regulatory Affairs Pfizer Inc. 400 Arcola Road Collegeville, PA 19426



Global Product Development

02 August 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 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: BLA 125742

COVID-19 mRNA Vaccine (BNT162/PF-07302048)

Follow up Response to 22 July 2021 Information Request

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 19 May 2021 for the COVID-19 mRNA Vaccine (BNT162/PF-07302048) developed by BioNTech and Pfizer under BB-IND 19736 for the prevention of COVID-19 caused by SARS-CoV-2 in individuals \geq 16 years of age.

The purpose of this submission is in response to CBER's 22 July 2021 Information Request to Pfizer, received via email from Laura Gottschalk, PhD (CBER). The requests were regarding clinical shell tables for study C4591001 which Pfizer provided responses on 26 and 28 July 2021. Pfizer further committed to provide additional sensitivity analysis by 02 August 2021 in response to question 5b. Pfizer's follow up Response to CBER 22 July 2021 Information Request for Study C4591001 is provided in Module 1.11.3.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 215-280-5503; via facsimile at 845-474-3500; or via e-mail at elisa.harkinstull@pfizer.com.

Sincerely,

Marion Gruber, Ph.D., Director BLA 125742

Elisa Harkins Global Regulatory Lead Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D.

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