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



Global Product Development

19 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)

Response to CBER 18 August 2021 Information Request Regarding Identification of BLA Compliant Lots and Dear HCP Letter

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) submitted 18 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 to respond to CBER's 18 August 2021 request received via email from Ramachandra Naik, Ph.D. (CBER) to submit to the BLA the graphic for identification of BLA-compliant lots and Dear HCP letter previously communicated by email from Donna Boyce, Senior Vice-President, Head of Global Regulatory Affairs, Pfizer Inc. to Mary Malarky, Director, OCBQ/FDA on 16 August 2021. The Response to FDA 18 August 2021 Information Request is provided in Module 1.11.4.

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.

Marion Gruber, Ph.D., Director BLA 125742

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Sincerely,

Elisa Harkins Global Regulatory Lead Global Regulatory Affairs – Vaccines

CC: Ramachandra S. Naik, Ph.D. Captain Michael Smith, Ph.D. Laura Gottshalk, Ph.D.