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

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 ≥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.

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.