Pfizer Global Regulatory Affairs
Pfizer Inc.
235 East 42nd Street/New York, NY 10017-5755

Global Product Development

17 September 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 125742/11

COMIRNATY (COVID-19 mRNA Vaccine)

General Correspondence – Correction to Previously Submitted Documents

Dear Dr. Gruber,

Reference is made to the Biologics License Application (BLA) 125742 for COMIRNATY (COVID-19 mRNA Vaccine), developed by BioNTech and Pfizer for the prevention of COVID-19 caused by SARS-CoV-2 in individuals ≥16 years of age issued on 23 August 2021.

Reference is also made to the Response to FDA 17 August 2021 Information Request Regarding Drug Substance (b) (4) and Drug Product (b) (4) (b) (4) at Kalamazoo and Puurs submitted formally on 19 August 2021.

The purpose of this submission is to correct drug substance documents submitted as a part of this response. Three draft drug substance documents were inadvertently linked to this response. This correspondence reverts these draft documents back to the previously approved documents. In support of this correspondence, the following documents are now reverted to the indicated sequence:

- Module 3, 3.2.S.2.2, Description of Manufacturing Process and Process Controls [Andover], sequence 0019
- Module 3, 3.2.S.2.4, Control of Critical Steps and Intermediates, sequence 0002
- Module 3, 3.2.S.2.6, Manufacturing Process Development – Process Development and Characterization, sequence 0002

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, or require additional information, please contact me via phone at 214-918-5262 or via e-mail at Amitkumar.Patel@pfizer.com.

Sincerely,

Amit Patel
Director
Global Regulatory Affairs - Vaccines

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