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

Global Product Development

15 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 125742/8

COMIRNATY (COVID-19 mRNA Vaccine)

WAIVER REQUEST – LOT DISTRIBUTION REQUIREMENTS

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.

Per 21 CFR 600.81 a Lot Distribution Report (LDR) is to be provided in electronic format every six months or at times other than every 6 months as determined at the time of approval. For COMIRNATY, the LDR was requested monthly per the BLA approval issued on 23 August 2021. The purpose of this General Correspondence is to request an extension of the first reporting period as well as a waiver to the monthly reporting requirement.

A Module 1, 1.12.5 Request for a waiver – Lot Distribution Reports is included and contains a justification for the waiver.

Pfizer respectfully request a response to this waiver request within 14 days.

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.