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

Global Product Development

15 October 2021

Marion Gruber, Ph.D.
Director
Food and Drug Administration
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
c/o Central Document Room
10903 New Hampshire Avenue, WO71-G112
Silver Spring, MD 20993-0002

Re: BLA 125742/30

COMIRNATY (COVID-19 mRNA Vaccine)

Summary Monthly Safety Report

Dear Dr. Gruber,

Pursuant to 21 CFR 600.80 (c)(2), enclosed is the Summary Monthly Safety Report in lieu of a quarterly Periodic Adverse Event Report, for the subject COMIRNATY (Covid-19 mRNA Vaccine) listed above. The time period covered by this report is from September 01, 2021 to September 30, 2021.

Please note that all periodic Individual Case Safety Reports (ICSRs) relevant to this application number were filed separately in electronic E2B format through FDA's Electronic Submission Gateway.

Pfizer considers the information submitted for BLA 125742/30 to be complete. Pfizer is committed to respond to the reviewers' questions promptly and to work with the Division as needed to facilitate this review.

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 please contact me via phone at 214-918-5262; or via email at Amitkumar.Patel@pfizer.com.

Sincerely,

Amit Patel
Director
Global Regulatory Affairs – Vaccines