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 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 125742/9

COMIRNATY (COVID-19 mRNA Vaccine)

Request for Comments and Advice – Biologic Product Deviation Reports (BPDRs)

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.

The purpose of this request for comments and advice is to obtain agreement with the Agency for reporting of Biologic Product Deviation Report to the Emergency Use Authorization as well as to the BLA.

A Module 1, 1.12.4 Request for Comments and Advice – BPDRs is included.

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.

Marion Gruber, Ph.D., Director BLA 125742

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.