



Global Product Development

28 January 2022

Peter Marks, M.D. Ph.D.
Acting 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 125742/45

COMIRNATY (COVID-19 mRNA Vaccine)

Subject: Response to 25 January 2022 Information Request to Provide a Revised 356h and Environmental Assessment or Claim of Categorical Exclusion

Dear Dr. Marks,

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 16 December 2021 Supplemental Biologics License Application to expand the indication of COMIRNATY to include adolescents 12 to 15 years of age and to the 25 January 2022 Information Request requesting a revised FDA form 356h that includes information regarding all establishments and manufacturing facilities, and an Environmental Assessment or Claim of Categorical Exclusion. This submission includes a revised 356h with the requested information. In addition, a Module 1, [1.12.14](#) Request for Categorical exclusion is provided.

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 (b) (6) or via e-mail at Adrienne.Stafford@pfizer.com.

Sincerely,

Adrienne Stafford
Director
Global Chemistry Manufacturing and Controls - Vaccines

CC: Ramachandra S. Naik, Ph.D.
CC: Laura Gottschalk, Ph.D.
CC: Captain Michael Smith, Ph.D.
CC: Sarah Lee, MPH
CC: Iryna Zubkova, Ph.D.