



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

Global Product Development

27 April 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: Emergency Use Authorization (EUA) 27034

Pfizer-BioNTech COVID-19 Vaccine

Response to FDA 25 April 2021 Information Request

Dear Dr. Gruber,

Reference is made to the Emergency Use Authorization (EUA) for Pfizer-BioNTech COVID-19 Vaccine for the active immunization to prevent COVID-19 in individuals ≥ 16 years of age and older issued on 11 December 2020. Reference is also made to the Amendment submitted 09 April 2021 to extend the indication to individuals 12-5 years of age.

Further reference is made to the Information Request (IR) received from the Agency on 25 April 2021 regarding safety follow-up time and case narratives for adverse events/serious adverse events after administration of Pfizer-BioNTech COVID-19 Vaccine.

The present submission provides [Response to FDA 25 April 2021 IR](#) in Module 1.11.3.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 212-733-2613; via facsimile at 845-474-3500; or via e-mail at neda.aghajanimemar@pfizer.com.

Sincerely,

Neda Aghajani Memar, Pharm.D.
Director
Pfizer Global Regulatory Affairs

CC: Ramachandra S. Naik, Ph.D.
CC: Laura Gottschalk, Ph.D.