



Pfizer Global Regulatory Affairs
Pfizer Inc.
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Global Product Development

22 April 2021

Marion Gruber, Ph.D.
Director
Office of Vaccines Research and Review
Food and Drug Administration
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Re: Emergency Use Authorization (EUA) 27034

Pfizer-BioNTech COVID-19 Vaccine

Response to FDA 20 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. Further reference is made to the Amendment submitted 09 April 2021 to extend the indication to individuals 12-5 years of age.

Reference is also made to the Information Request (IR) received from the Agency on 20 April 2021 regarding data analysis programs and datasets submitted on 09 April 2021.

The present submission provides [Response to FDA 20 April 2021 Information Request](#) in Module 1.11.3.

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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.aghajanimehar@pfizer.com.

Sincerely,

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

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