



Pfizer Global Regulatory Affairs
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Global Product Development

06 May 2021

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Re: Emergency Use Authorization (EUA) 27034

Pfizer-BioNTech COVID-19 Vaccine

Response to FDA 05 May 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 on 9 April 2021 (sequence 0135) to extend the EUA of the Pfizer-BioNTech COVID-19 Vaccine to individuals 12 through 15 years of age

Further reference is made to the Information Request (IR) received from the Agency on 05 May 2021 to request subgroup analyses of solicited local reactions and systemic AEs, based on sex (M/F), race, and ethnicity, in adolescents 12 through 15 years of age.

The present submission provides [Response to FDA 05 May 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.