



Pfizer Global Regulatory Affairs
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Global Product Development

03 May 2021

Marion Gruber, Ph.D.
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Re: Emergency Use Authorization (EUA) 27034

Pfizer-BioNTech COVID-19 Vaccine

General Correspondence

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 the protocol for study C4591001 entitled, “*A Phase 1/2/3, Placebo-Controlled, Randomized, Observer-Blind, Dose-Finding Study to Describe the Safety, Tolerability, Immunogenicity, and Efficacy of SARS-CoV-2 RNA Vaccine Candidates Against COVID-19 in Healthy Individuals*”.

[Attached](#) please find a copy of a presentation that was given to the ACIP Working Group on 28 April 2021. This presentation was also provided to the Agency via email on 30 April 2021.

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.