



Pfizer Global Regulatory Affairs
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Global Product Development

29 April 2021

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Director
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Re: Emergency Use Authorization (EUA) 27034

Pfizer-BioNTech COVID-19 Vaccine

Labeling Change - EUA Prescribing Information

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 FDA's comments on the draft Full EUA Prescribing Information and Fact Sheet received via email on 23 April 2021 and 28 April 2021.

The present submission provides the following in Module 1.14.1:

- Updated Fact Sheet for Healthcare Providers and Full EUA Prescribing Information
 - Track change ([Word](#))
 - Annotated ([PDF](#))
 - Clean copy ([PDF](#) and [Word](#))

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.