



## Global Product Development

11 May 2021

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**Re: Emergency Use Authorization (EUA) 27034**

**Pfizer-BioNTech COVID-19 Vaccine**

**Final Labeling – EUA Prescribing Information**

**Structured Product Labeling**

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  $\geq 12$  years of age and older issued on 10 May 2021. Reference is also made to the following revisions approved via email on 10 May 2021 for the prevention of COVID-19 in individuals 12 through 15 years of age:

Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers) is revised to include the following Warning: “Syncope (fainting) may occur in association with administration of injectable vaccines, in particular in adolescents. Procedures should be in place to avoid injury from fainting.” The Fact Sheet for Recipients and Caregivers is revised to instruct vaccine recipients or their caregivers to tell the vaccination provider about fainting in association with a previous injection.

Enclosed in this submission in Module 1.14.2 are the final clean copy ([PDF](#) and [Word](#)) for the Healthcare Provider Fact Sheet/Full EUA Prescribing Information and the final clean copy ([PDF](#) and [Word](#)) for the Recipient and Caregiver Fact Sheet that include all of the revisions referenced above.

Additionally, the present submission provides the Structured Product Labeling for the combined Healthcare Provider Factsheet/Full EUA Prescribing Information Recipient and Caregiver Fact Sheet in Module 1.14.2.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

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](mailto: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.  
CC: Michael Smith, Ph.D.