

Laura B. Gottschalk -S
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From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>
Sent: Thursday, May 20, 2021 10:19 PM
To: 'Aghajani Memar, Neda' <Neda.AghajaniMemar@pfizer.com>
Cc: Devlin, Carmel M <Carmel.Devlin@pfizer.com>; Harkins Tull, Elisa <Elisa.HarkinsTull@pfizer.com>; Gottschalk, Laura <Laura.Gottschalk@fda.hhs.gov>; Smith, Michael (CBER) <Michael.Smith2@fda.hhs.gov>
Subject: EUA 27034 - Pfizer-BioNTech COVID-19 Vaccine – Accuracy of data in Table P (EUA 27034.132 submission)

Dear Ms. Aghajani Memar,

Reference is made to the amendment 132 (dated April 9, 2021) to EUA 27034 to extend the emergency use authorization of the Pfizer-BioNTech COVID-19 Vaccine to individuals 12 through 15 years of age. We have the following Comment:

In Table P. Demographics and Other Baseline Characteristics, Participants 12 to 15 and 16 Through 25 Years of Age (Reactogenicity Subset), Safety Population, from the c4591001-508 compliant tables 12-15 document, please confirm the accuracy of the data for the rows describing Obesity and Baseline Evidence of Prior SARS-CoV-2 Infection. The percentages of participants 16-25 Years who were “Baseline Evidence of Prior SARS-CoV-2 Infection: Positive” are reported as 93% in the vaccine group and 93% in the placebo group. As a comparison, the baseline positive percentages for participants 12-15 Years were 4.1% (vaccine group) and 4.2% (placebo group).

Please submit the updated table as soon as possible as an amendment to your EUA 27034.

Please confirm receipt of this email and let me know if you have any questions or need additional information.

Regards,
Ram

Ramachandra S. Naik, Ph.D.

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