

Laura B. Gottschalk -S
2021.05.05 19:54:39 -04'00'

From: Naik, Ramachandra <Ramachandra.Naik@fda.hhs.gov>

Sent: Wednesday, May 5, 2021 7:09 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: [EXTERNAL] EUA 27034.132 - Pfizer-BioNTech COVID-19 Vaccine - CBER comments regarding subgroup analyses of solicited local reactions and systemic AEs, based on sex (M/F), race, and ethnicity

Dear Ms. Aghajani Memar,

Reference is made to the amendment 132 (dated April 9, 2021) to your 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:

Please provide 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.

Please submit your response to the above comment as an amendment to your EUA 27034 by 12:00 PM Thursday, May 6, 2021.

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.

Biologist (Regulatory) / Primary Reviewer

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