



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Ramachandra
Naik -S

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Food and Drug Administration
Silver Spring, MD 20993

**CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF VACCINES RESEARCH AND REVIEW
DIVISION OF VACCINES AND RELATED PRODUCTS APPLICATIONS**

DATE: April 25, 2021 **PAGES:** 2

TO: **Pfizer. Inc./BioNTech SE**
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FROM: **Ramachandra Naik, Ph.D.**
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CBER Reference: EUA 27034 amendment 132

EUA Title: Human Coronavirus mRNA Vaccines (SARS-CoV-2 Spike Protein; BNT162b2) in Lipid Nanoparticles (ALC-0315, ALC-0159, DSPC and Cholesterol) (Pfizer-BioNTech COVID-19 Vaccine)

SUBJECT: CBER comments regarding safety follow-up time and case narratives for AEs/SAEs

Dear Ms. Harkins:

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 comments:

1. For the age group of participants 16-25 years of age, please provide the number of participants who contributed to the safety population (total and by treatment group)

and percentage of participants with greater than or equal to 2 months, and greater than or equal to 1 month of blinded follow up after Dose 2. Please also present these data in table format similar to the 12-15 years age group, presented in Table 3, page 20 of the document m1.19 eua-amend-12-15-years.pdf.

2. For participants 16-55 years of age (document c4591001-16-55-tables-2.pdf, page 9), please provide case narratives for 19 subjects reporting a life-threatening SAE (n=8 BNT162b2, n=11 placebo), 16 subjects who withdrew from the study due to an AE related to vaccination (n= 9 BNT162b2, n=7 placebo), and for 2 deaths in placebo participants. If any of the narratives were provided in the initial EUA (27034/0) and there is no updated information, please provide only the subject ID numbers.

Please submit your responses to the above comments as an amendment to your EUA 27034 by 12:00 PM Tuesday, April 27, 2021.

If you have any questions, please contact me by email: ramachandra.naik@fda.hhs.gov or at 301-796-2640.