



Ramachandra
Naik -S

Digitally signed by
Ramachandra Naik -S
Date: 2021.04.27 10:47:11
-04'00'

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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 27, 2021 **PAGES:** 2

TO: **Pfizer. Inc./BioNTech SE**
Attention: Neda Aghajani Memar
235 East 42nd Street, 219/9/69
New York, NY 10017
Phone: 212-733-2613
Fax number: 845-474-3500
E-mail: Neda.Aghajani.Memar@pfizer.com

FROM: **Ramachandra Naik, Ph.D.**
Division of Vaccines and Related Products Applications
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
Phone number: 301-796-2640
Fax number: 301-595-1244

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 immediate AEs and number of participants completed the 6 months safety follow-up

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. Immediate AEs for participants 16-25 years of age:
Please provide, based on the safety population (excluding 1 HIV-positive subject), summary tables of the number (%) of subjects reporting at least 1 immediate AEs after Dose 1 and after Dose 2, by System organ class and preferred term. (Similar to c4591001-12-15-tables-figure.pdf, pages 124-125).
2. In the EUA amendment summary (eua-amend-12-15-years.pdf, page 54), Table 13 indicates that 10.4% of BNT162b2 subjects had ≥ 6 months safety follow-up, but the text in section 6.2.2.1.2.1.3 (Disposition – Adults 16-55 Years of Age) states that 25.5% of the BNT162b2 group participants completed the 6 months post Dose 2. Please clarify this apparent discrepancy, and if needed, revise Table 13.

Please submit your responses to the above comments as an amendment to your EUA 27034 by 12:00 PM Wednesday, April 28, 2021.

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