



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

DATE: April 30, 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 physical exam findings, case narratives for subjects with psychiatric diagnoses and deep vein thrombosis

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 comments:

1. For subject # 1007 10071620 (neuralgia)- include details of physical exam findings, including neurological findings, psychologist's conclusions, and clinical laboratory evaluations, diagnosis, treatments administered and outcome.
2. Please submit detailed case narrative comments and all available clinical information, to include any physical and psychiatric examinations, and hospital summaries, diagnosis, treatments administered and outcomes, for each of the eighteen subjects (12 in vaccine group and 6 in the placebo group) with events listed under the Preferred Term "Psychiatric Disorders" from Table 8 of the eua-amend-12-15-years.pdf submitted to EUA 27034 in amendment 132 on April 9, 2021.
3. Please submit detailed case narrative comments and all available clinical information, to include any physical and psychiatric examinations, and hospital summaries, diagnosis, treatments administered and outcomes, for each of the thirteen subjects (8 in vaccine group and 6 in placebo group) with events listed under the Preferred Term "Psychiatric Disorders" from Table 9 of the eua-amend-12-15-years.pdf submitted to EUA 27034 in amendment 132 on April 9, 2021.
4. Please submit detailed case narrative comments and all available clinical information, to include any physical and psychiatric examinations, and hospital summaries, diagnosis, treatments administered and outcomes for each of the five subjects with events listed under the Preferred Term "Psychiatric Disorders" from Table 11 of the eua-amend-12-15-years.pdf submitted to EUA 27034 in amendment 132 on April 9, 2021.
5. Provide a table displaying baseline demographic information about the safety population in participants 12-15 years of age, by treatment group, to show numbers and percentage of participants with known history of any psychiatric diagnoses, in addition to specific diagnoses of depression, anxiety, generalized anxiety disorder, or history of suicidal ideation, and current status of these conditions (active, under treatment, inactive) at the time of enrollment.
6. For subject 16-55 year of age, please provide detailed case narrative comments for 8 BNT162b2 and 8 placebo participants with deep vein thrombosis, including clinical laboratory results for platelet counts, treatments administered and outcomes.

Please submit your responses to the above comments as an amendment to your EUA 27034 by 12:00 PM on Monday, May 3, 2021.

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