Our STN: BL 125769/466

NOTIFICATION OF NON-COMPLIANCE WITH PREA
March 24, 2025

Pfizer Inc.
Attention: Helen B. Hartman, Ph.D.
500 Arcola Road,
Collegeville, PA 19426

Dear Dr. Hartman:

Please refer to your supplement to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Respiratory Syncytial Virus Vaccine (ABRYSVO).

The Agency has determined that you have failed to meet the postmarketing requirements (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not submitted your nonclinical final study report for PMR #4, which was deferred until September 30, 2024. Therefore, we are hereby notifying you that due to your failure to submit either a final study report, or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of Title V, Section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reasons for the delayed pediatric assessment and a date by which you expect to submit the assessment.

You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

We note that you requested a deferral extension on February 10, 2025; however, we have determined that your request was not submitted at least 90 days prior to the deferral expiration.

In accordance with FDASIA, FDA will post this letter and your response on the website located at https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CBER/ucm448393.htm with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please submit your response to this letter within 45 days to this STN BL 125769/466. Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit a cross-reference letter to the IND to which your protocol has been submitted.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

If you have any questions, please contact the Regulatory Project Manager, Dr. Goutam Sen, by email at Goutam.Sen@fda.hhs.gov.

Sincerely,

R. Douglas Pratt, MD, MPH
Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research