Our STN: BL 125549/774

NOTIFICATION OF NON-COMPLIANCE WITH PREA

July 8, 2021

Wyeth Pharmaceuticals, Inc.
Attention: Malgorzata Gosia Mineo, MS
Pfizer, Inc.
401 N. Middletown Road
Pearl River, NY 10965

Dear Ms. Mineo:

Please refer to your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Meningococcal Group B Vaccine.

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 yet submitted your pediatric assessments for PMR#5 from the approval letter for STN BL 125549/0, and PMR #2 from the approval letter for STN BL 125549/17, which were deferred until May 31, 2021.

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 assessments and a date by which you expect to submit the assessments.

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 125549. 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, Ms. Helen Gemignani, at helen.gemignani@fda.hhs.gov.

Sincerely,

Loris D. McVittie, Ph.D.
Deputy Director - Regulatory
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research