Our STN: BL 125251/272

NOTIFICATION OF NON-COMPLIANCE WITH PREA
September 8, 2021

OCTAPHARMA Pharmazeutika Produktionsges.m.b.H.
Attention: Stanley Ammons
Octapharma USA, Inc.
117 West Century Road
Paramus, NJ 07652

Dear Mr. Ammons:

Please refer to your supplement to your Biologics License Application (BLA) submitted and received December 18, 2019, under section 351(a) of the Public Health Service Act for von Willebrand Factor/Coagulation F VIII Complex.

The Agency has determined that you have failed to meet the postmarketing requirement (PMR) of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment for PMR #1, which was deferred until December 31, 2019. Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment 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 reason(s) 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.

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 125251/272. 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, Catherine Tran, at catherine.tran@fda.hhs.gov.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research