



Our STN: BL 125546/347

**NOTIFICATION OF  
NON-COMPLIANCE WITH PREA**

GlaxoSmithKline Biologicals  
ATTENTION: Freddie De Brito, Ph.D.  
14200 Shady Grove Road, VR1500  
Rockville, MD 20850-7464

April 16, 2018

Dear Dr. De Brito

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

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 3, which was deferred until March 31, 2018. 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 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 125546/347. 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.

If you have any questions, please contact the Regulatory Project Manager, CAPT Edward Wolfgang, Ph.D., at (301) 796-2640.

Sincerely yours,

Wellington Sun, M.D.  
Director  
Division of Vaccine and  
Related Product Application  
Office of Vaccines and  
Research and Review  
Center for Biologics  
Evaluation and Research