April 25, 2018

Marion F. Gruber, Ph.D., Director
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RESPONSE TO NOTIFICATION OF PREA NON-COMPLIANCE LETTER; DEFERRAL EXTENSION REQUESTED

Re: STN: BL 125546; Bexsero (Multicomponent Meningococcal group B Vaccine (recombinant, adsorbed)
US License No. 1617

Dear Dr. Gruber,

With this letter and the enclosed PREA extension deferral request, GSK is responding to the non-compliance letter dated 16April2018, as well as initiating a request for deferral extension.

GSK has diligently pursued development of Bexsero in children from the time of approval of Bexsero to the present time. We have been working directly with CBER to ensure that our pediatric development plans and protocols will support fulfillment of the commitment as well as meet expectations for licensure. This alignment activity is well documented in numerous submissions and correspondences, as well as meetings, and includes status updates for the PREA study as well as a request for PMC extension (see update sequences **List A** enclosed).

GSK acknowledges that the request for PMC extension was not submitted in a way that met CBER expectations for handling as a PREA extension. We appreciate the guidance we have received from our CBER contacts and are hereby taking steps to address this oversight on our part. We are actively working to complete our PREA assessment and with the enclosed deferral extension request we are including our status update and proposed timeline with a completion date of November 15, 2023.

It is our understanding that upon receipt of this request for deferral extension for the Post-Marketing Requirement #3, a PREA study evaluating Bexsero in infants aged 6 weeks through 12 months of age, CBER will consider the request at a meeting of the appropriate committee and provide feedback to GSK. It is also our understanding that with a grant of extension within the 45 days stated in our notice, the notice letter will not be posted publicly.

GSK requests acknowledgement of receipt of this letter and the request for deferral extension. We look forward to receiving the outcome of the review.
We are available at any time to support questions and comments.

Sincerely,

/s/

/s/

Kimberly Poffenberger, Ph.D.
VP, Head Region US RA
Global Regulatory Affairs
Vaccines

Frederick De Brito, Ph.D., M.B.A.
Director, Region US RA
Global Regulatory Affairs
Vaccines

Enclosures:

LIST A. Relevant interactions with CBER regarding the PREA study V72_57

LIST B. CBER correspondence with GSK regarding the PREA study V72_57