Pfizer Global Regulatory Affairs
Pfizer Inc
401 N. Middletown Rd
Pearl River, NY 10965

Global Product Development

22 July 2021

Food and Drug Administration
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research
c/d Central Document Room
10903 New Hampshire Avenue, WO71-G112
Silver Spring, MD 20993-0002

Re: BLA 125549 for TRUMENBA® (Meningococcal Group B Vaccine)

Response to PREA PMR Non-Compliance Letter

Dear Director:

Reference is made to the Investigational New Drug (IND) Application (BB-IND 13812) and Biologics License Application (STN: BL 125549) for Trumenba® (Meningococcal Group B Vaccine), for which approval was received on October 29, 2014 with indication for active immunization of individuals aged 10 through 25 years to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. On April 14, 2016 a sBLA (STN: BL 125549/17) to include the 2-dose schedule (a dose administered at 0 and 6 months) was approved for individuals aged 10 through 25 years, with a commitment to complete a Phase 3 study of the two-dose schedule. An sBLA (STN: BL 125549/737) containing the results of this study (B1971057) was submitted on September 11, 2020.

Reference is also made to Pfizer's committment (PREA; 21 U.S.C. 355c) to evaluate the safety and immunogenicity of Trumenba, both the 2- and 3-dose regimens, in children 1 year to <10 years of age for the prevention of invasive group B meningococcal disease (FDA PMR#5 of the October 29, 2014 initial BLA approval for the 3-dose regimen; FDA PMR#2 of the March 13, 2017 sBLA approval for the 2-dose regimen).

This study identified as B1971051 is a deferred pediatric study under PREA. Based on the March 13, 2017 approval letter (STN: BL 125549/17; PMR#2) the Final protocol submission date was May 31, 2018, Study completion was December 30, 2020 and Final Report Submission May 31, 2021. These commitment milestone dates were also applied to the initial BLA approval PMR#5 (Deferral Extension Requested November 19, 2019; Deferral Extension Approved December 18, 2019).

Reference is made to the (b) (4)

Reference is also made to the PREA PMR Non-Compliance Letter received on 9 July 2021 concerning the aforementioned deferred pediatric study B1971051.

Pfizer submitted a request on 28 May 20201 to BLA 125549 (b) (4) This submission included the 1.17.2 Correspondence Regarding Postmarketing Requirements providing more details on the request. The same 1.17.2 Correspondence Regarding Postmarketing Requirements is provided with this submission for complete response.

This submission has been scanned for viruses using McAfee VirusScan Enterprise Version 8.8 and is virus free. The submission is being sent via the Gateway.

Should you have any questions regarding this submission, or require additional information, please contact me via phone at 973-307-8389; via facsimile at 845-474-3500; or via email at gosia.mineo@pfizer.com.

Sincerely,

Malgorzata (Gosia) Mineo, MS
Director
Global Regulatory Affairs - Vaccines
Pfizer, Inc.
as agent for Wyeth Pharmaceuticals LLC

cc: Captain Michael Smith, PhD