**Trumenba® (Meningococcal Group B Vaccine)**

**1.17.2 Correspondence Regarding Postmarketing Requirements**

**B1971057**

**STN: BL 125549**

**May 2021**

## 1. INTRODUCTION

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). Trumenba was approved October 29, 2014 under 21 Code of Federal Regulations (CFR) 601 Subpart E - *Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses* (STN: BL 125549) for active immunization of individuals aged 10 through 25 years to prevent invasive disease caused by *Neisseria meningitidis* serogroup B. As a requirement of licensure, the clinical benefit of Trumenba was confirmed by demonstration of effectiveness against diverse meningococcal group B strains in Phase 3 studies.

A supplemental BLA (sBLA), containing the results of the completed Phase 3 studies, was approved on March 13, 2017 converting the Trumenba license for the 3-dose regimen to Traditional Approval.

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, also under 21 CFR 601 Subpart E, 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.

In accordance with the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), Pfizer has committed 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 is a deferred pediatric study (B1971051) under PREA to evaluate the safety and immunogenicity of Trumenba in children 1 year to <10 years of age for the prevention of invasive group B meningococcal disease. 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).

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