SUPPLEMENT APPROVAL
PMR and PMC FULFILLED

OUR STN: BL 125549/173

Wyeth Pharmaceuticals, Inc.
Attention: Elisa Harkins
500 Arcola Road
Collegeville, PA 19426

March 13, 2017

Dear Ms. Harkins:

We have approved your request dated May 13, 2016, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Meningococcal Group B Vaccine (Trumenba®) to include data from two confirmatory clinical studies to verify and describe the clinical benefit of the three-dose schedule (a dose administered at 0, 1-2, and 6 months) of Trumenba. Also, we have approved your request to include data from a study to further describe the safety of Trumenba in persons 10 years to less than 26 years of age, and a study to assess the concomitant use of Trumenba with Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed in persons 10 years to less than 13 years of age.

We approved BLA STN 125549/0 on October 29, 2014, under 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement fulfills the following postmarketing requirements for the three-dose schedule for Trumenba made under 21 CFR 601.41:

1. To conduct the ongoing study (B1971009) among persons 10 years to less than 19 years of age to confirm effectiveness against a panel of diverse meningococcal group B strains.

   Final Protocol Submission: February 20, 2013

   Study Completion: April 17, 2015

   Final Report Submission: December 30, 2015

2. To conduct the ongoing study (B1971016) among persons 18 years to less than 26 years of age to confirm the effectiveness against a panel of diverse meningococcal group B strains.

   Final Protocol Submission: December 20, 2013

Study Completion: February 13, 2015

Final Report Submission: December 30, 2015

The review of this supplement was associated with the following National Clinical Trial (NCT) number(s): NCT01352793, NCT01352845, NCT01461980 and NCT01830855.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 125549/173.10 dated March 10, 2017.

Please provide your final content of labeling in Structured Product Labeling (SPL) format and include the carton and container labels. In addition, please submit three original paper copies for carton and container final printed labeling. All final labeling should be submitted as Product Correspondence to BLA STN 125549 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in SPL format via the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71-G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

This submission fulfills your postmarketing commitments 6 and 7, identified in the October 29, 2014, approval letter for STN 125549/0 for Trumenba. The commitments addressed in this submission are as follows:

6. To conduct the ongoing safety and immunogenicity study (B1971015) to assess concomitant use of Trumenba with Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine and Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed in persons 10 years to less than 13 years of age.

   Final Protocol Submission: November 5, 2012

   Study Completion: May 8, 2014

   Final Report Submission: May 30, 2015

7. To conduct the ongoing controlled study (B1971014) to further describe the safety of Trumenba in persons 10 years to less than 26 years of age.

   Final Protocol Submission: August 2, 2012

   Study Completion: September 26, 2014

   Final Report Submission: June 30, 2015

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research