Our STN: BL 125549/737

SUPPLEMENT APPROVAL
PMR FULFILLED

Wyeth Pharmaceuticals, LLC
Attention: Malgorzata (Gosia) Mineo
401 N. Middletown Road
Pearl River, NY 10965

November 19, 2021

Dear Ms. Mineo:

We have approved your request submitted and received on September 11, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Meningococcal Group B Vaccine (Trumenba) manufactured at your (b) (4) facility, to include data from the confirmatory clinical study conducted to verify and describe the clinical benefit of the two-dose schedule (a dose administered at 0 and 6 months) of Trumenba in individuals 10 through 25 years of age.

We approved BLA STN BL 125549/17 on April 14, 2016, 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 requirement for the two-dose schedule of Trumenba in individuals 10 through 25 years of age made under 21 CFR 601.41:

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

1. To conduct a study to assess safety, tolerability, and immunogenicity of Trumenba administered on a 0-, 6-month schedule in healthy subjects aged ≥10 to <26 years.

   Final Protocol Submission: June 30, 2016

   Study/Trial Completion: August 31, 2019

   Final Report Submission: December 31, 2019

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT03135834.

LABELING

We hereby approve the draft content of Package Insert labeling submitted under amendment 7, dated November 16, 2021.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the Package Insert submitted on November 16, 2021. 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.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125549, at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

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.

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

Sincerely,

Doran L. Fink, M.D., Ph.D.
Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research