Our STN: BL 125546/1058

SUPPLEMENT APPROVAL
PMRs FULFILLED
August 19, 2024

GlaxoSmithKline Biologicals
Attention: Wendy Valinski
14200 Shady Grove Road
VR1500
Rockville, MD 20850-7464

Dear Ms. Valinski:

We have approved your request received July 21, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Meningococcal Group B Vaccine (BEXSERO) manufactured at your facility located in Sovicille (Rosia), Italy to include data from the confirmatory clinical study conducted to verify and describe the clinical benefit of BEXSERO. The BEXSERO dosing schedule has been revised in individuals 10 through 25 years of age from two doses administered at 0 and ≥1 month to two doses administered at 0 and 6 months, and to include a three-dose schedule of BEXSERO administered at 0, 1-2, and 6 months for the same age group.

We approved BLA STN BL125546/0 on January 23, 2015, 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 BEXSERO made under 21 CFR 601.41:

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

1. To conduct the ongoing study V102_16 to assess the performance of immunologic assays for evaluating the breadth of coverage against diverse *Neisseria meningitidis* serogroup B strains.

   Final Protocol Submission: November 19, 2013

   Study Completion: May 28, 2015

   Final Report Submission: March 20, 2016

2. To conduct study V72_72 of BEXSERO among persons 10 years through 25 years of age in the US to confirm effectiveness against a panel of diverse *Neisseria meningitidis* serogroup B strains.

   Final Protocol Submission: December 31, 2015

Study Completion: December 31, 2017

Final Report Submission: December 31, 2018

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT04502693.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 38, dated August 19, 2024.

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 August 19, 2024. 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 125546, 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are deferring submission of your pediatric studies for children 6 weeks to less than 10 years of age for this application because the product is ready for approval for use in individuals 10 through 25 years of age and the studies in children 6 weeks to less than 10 years of age have not been completed.

Your deferred pediatric studies required under section 505B(a) of the Federal Food, Drug, and Cosmetic Act (FDCA) are required postmarketing studies. The status of these postmarketing studies must be reported according to 21 CFR 601.28 and section 505B(a)(3)(B) of the FDCA. In addition, section 506B of the FDCA and 21 CFR 601.70 require you to report annually on the status of any postmarketing commitments or required studies or clinical trials.

Label your annual report as an **Annual Status Report of Postmarketing Study Requirement/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of BLA STN BL 125546 until all requirements and commitments subject to the reporting requirements under section 506B of the FDCA are released or fulfilled. These required studies are listed below:

1. A deferred pediatric study (V72_28E1) under PREA to evaluate the safety and immunogenicity of BEXSERO in children >1 year through 9 years of age.

   Study Completion: November 17, 2015

   Final Report Submission: August 31, 2024

2. A deferred pediatric study (V72P12E1) under PREA to evaluate the safety and immunogenicity of BEXSERO in children >1 year through 9 years of age.

   Study Completion: September 1, 2012

Final Report Submission: August 31, 2024

3. A deferred pediatric study (V72P12E2) under PREA to evaluate the safety and immunogenicity of BEXSERO in children >1 year through 9 years of age.

   Study Completion: October 28, 2013

   Final Report Submission: August 31, 2024

4. A deferred pediatric study (V72P13E2) under PREA to evaluate the safety and immunogenicity of BEXSERO in children >1 year through 9 years of age.

   Study Completion: September 8, 2011

   Final Report Submission: August 31, 2024

We remind you of your PREA PMRs identified in your January 23, 2015, BLA approval letter:

3. A deferred pediatric study (V72_57) under PREA to evaluate the safety and immunogenicity of BEXSERO in North American infants 6 weeks through 12 months of age for the prevention of invasive group B meningococcal disease.

   Final Protocol Submission: December 31, 2014

   Study Completion: June 30, 2017 (revised to August 31, 2025)

   Final Report Submission: March 31, 2018 (deferral extension until June 30, 2026, granted)

4. A deferred pediatric study (V72_28) under PREA to evaluate the safety and immunogenicity of BEXSERO in infants 2.5 months through 11 months of age and in children 2 years through 10 years of age for the prevention of invasive group B meningococcal disease.

   Final Protocol Submission: December 3, 2014

   Study Completion: December 31, 2014

   Final Report Submission: December 31, 2015 (submitted)

Submit final study reports to this BLA STN BL 125546. In order for your PREA PMRs to be considered fulfilled, you must submit and receive approval of either an efficacy or a labeling supplement. For administrative purposes, all submissions related to these required pediatric postmarketing studies must be clearly designated as:

- **Required Pediatric Assessment(s)**

This product is appropriately labeled for use in ages 10 to 17 years for this indication. Therefore, no additional studies are needed in this pediatric group.

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

Sincerely,

For Rebecca Reindel, M.D.
Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research