Our STN: BL 125300/922

SUPPLEMENT APPROVAL
March 31, 2025

GlaxoSmithKline Biologicals
Attention: Jennifer Sykora, Ph.D.
14200 Shady Grove Road
VR1500
Rockville, MD 20850-7464

Dear Dr. Sykora:

We have approved your request received November 29, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM_{197} Conjugate Vaccine (MENVEO) manufactured at your facility in Sovicille (Rosia), Italy, to include the following changes:

- Extension of the expiry dating period for the MenA lyophilized conjugate component of MENVEO from the currently approved 24 months to 48 months, when stored at 2°C to 8°C.
- A change in the assay used to determine (b) (4)
- Changes to: 1) the reconstitution instructions for the MENVEO two-vial presentation in the package insert (section 2 *Dosage and Administration*) and the carton label to remove the option for storage of MENVEO for up to 8 hours after reconstitution, and 2) the package insert (section 16, *How Supplied/ Storage and Handling*) to remove storage after reconstitution information regarding the MENVEO two-vial presentation.

LABELING

We hereby approve the draft content of labeling: Package Insert and the draft carton and container labels submitted on November 29, 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 in the original submission on November 29, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on November 29, 2024, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125300/922, 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.

We will include information contained in the above-referenced supplements in your BLA files.

Sincerely,

Jay E. Slater, M.D.
Director
Division of Bacterial, Parasitic and Allergenic Products
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research