Our STN: BL 125300/778

SUPPLEMENT APPROVAL

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

October 14, 2022

Dear Dr. Natilla:

We have approved your request received September 15, 2021, 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) to include a one-vial presentation of MENVEO manufactured at your GSK Vaccines facility S.R.L. in Sovicille, Italy, for active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroups A, C, Y, and W-135 in individuals 10 through 55 years of age.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: 03433482 and 03652610.

DATING PERIOD

The dating period for the one-vial presentation of MENVEO shall be 18 months from the date of manufacture when stored at 2-8°C. The date of manufacture shall be defined as the date of final sterile filtration of the formulated drug product. Following the final sterile filtration, no reprocessing/reworking is allowed without prior approval from the Agency.

COMPARABILITY PROTOCOLS

The approval also includes comparability protocols for (b) (4)

Under 21 CFR 601.12(e), approval of a comparability protocol may justify a reduced reporting category for a particular change. In your annual report (21 CFR 601.12(d)), you should report information confirming that the change(s) in the above reference standards or controls meets the requirements specified in your approved comparability protocol. Include the information described in 21 CFR 601.12(d)(3).

In exceptional circumstances (i.e., a supply impact that limits batches available to be used as standards or controls), batches of reference standards or controls which do not fully satisfy the agreed conditions as defined by the respective comparability protocol should be reported as a Supplement – Changes Being Effected in 30 Days (21 CFR 601.12(c)). You should include the information described in 21 CFR 601.12 (b)(3) in this supplement. Although you may distribute the product made using this change 30 days/immediately after FDA receives the supplement, continued use of the change will be subject to our final approval of the supplement.

LABELING

We hereby approve the draft content of labeling of the Package Insert, the two-vial presentation carton label and the one- and two-vial presentation container labels submitted under amendment 28, dated October 7, 2022, and the one-vial presentation carton label submitted under amendment 26, dated September 13, 2022.

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 October 7, 2022. 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 two-vial presentation carton and the one- and two-vial presentation container labels submitted on October 7, 2022, and the one-vial presentation carton label submitted on September 13, 2022, 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, 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,

For Rebecca Reindel, M.D.
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research