Our STN: BL 125300/627 **SUPPLEMENT APPROVAL**

GlaxoSmithKline Biologicals
Attention: Natalie Farris December 20, 2019
14200 Shady Grove Road
VR1500
Rockville, MD 20850-7464

Dear Ms. Farris:

We have approved your request submitted on February 20, 2019, and received on February 21, 2019, to supplement your Biologics License Application (BLA) 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 Sovicille (Rosia), Italy facility, to include safety and immunogenicity data to support revaccination of adolescents and adults and revisions to the package insert labeling to comply with 21 CFR 201.57 (c)(9)) i - iii and address the Pregnancy and Lactation Labeling Rule, to update Section 13.1, and to add other editorial changes throughout.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT 02986854, NCT 01018732, and NCT 01823536.

LABELING

We hereby approve the draft package insert labeling submitted under Amendment 8, dated September 27, 2019.

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. 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 125300 at the time of use (prior to marketing) 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