Our STN: BL 125300/494

SUPPLEMENT APPROVAL
[PMR/PMC FULFILLED]

GlaxoSmithKline Biologicals
Attention: Freddie De Brito, MBA, Ph.D.
350 Massachusetts Avenue
Cambridge, MA 02139-4182

October 6, 2016

Dear Dr. De Brito:

We have approved your request to supplement your biologics license application (BLA) for Meningococcal (Groups A, C, Y and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine (Menveo®), manufactured at your manufactured at your Rosia, Italy location, to update the package insert to include information regarding Bell's Palsy in the Postmarketing Experience section.

Please provide your final content of labeling in Structured Product Labeling (SPL) format. In addition, please submit three original paper copies for final printed labeling. All final labeling should be submitted as Product Correspondence to this BLA at the time of use (prior to marketing) and include implementation information on FDA Form 356h.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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 titled, "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

You may submit two draft copies of the proposed introductory advertising and promotional labeling with an FDA Form 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 advertisement 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.

This submission fulfills your postmarketing commitment #9 identified in the February 19, 2010, approval letter for STN 125300/0 for Menveo. The commitment addressed in this submission is as follows:

9. To conduct a Phase IV self-controlled case-series study to assess the safety of Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine administered to a minimum of 50,000 HMO subjects 11 through 19 years of age to expand the understanding of the safety profile of Meningococcal (Groups A, C, Y, and W-135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine. The final IRB approved study protocol will be submitted no later than June 20, 2010. The study will be initiated by August 20, 2010. The final study report will be submitted by 1 year after the last subject has completed the study and no later than August 20, 2015.

We will include information contained in the above-referenced supplement in your biologics license application file.

Sincerely yours,

Wellington Sun, M.D.
Director
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Attachment: Approved Final Draft Labeling