



Our STN: BL 125546/824

**SUPPLEMENT APPROVAL**

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

January 6, 2022

Dear Dr. Phillips:

We have approved your request submitted and received on July 8, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Meningococcal Group B Vaccine (BEXSERO) manufactured at your Sovicille (Rosia), Italy facility to update the Package Insert labeling to include language pertaining to "Lymphadenopathy" in section 6.2 (Postmarketing Experience) and to remove reference to the discontinued "Carton of 1" prefilled syringe presentation from section 16.1 (How Supplied).

**LABELING**

We hereby approve the draft content of Package Insert labeling submitted on July 8, 2021.

**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 July 8, 2021. 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes this change.

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