



## **SUPPLEMENT APPROVAL**

Our STN: BL 103239/5606

GlaxoSmithKline Biologicals  
Attention: Andrea Meeler  
14200 Shady Grove Road  
VR1500  
Rockville, MD 20850

December 19, 2018

Dear Ms. Meeler,

We have approved your request dated June 21, 2018, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Hepatitis B Vaccine Recombinant (ENGERIX-B) manufactured at your Rixensart, Belgium facility to update Section 8 of the package insert (PI) to comply with 21 CFR 201.57(c)(9)(i)-(iii) to address the Pregnancy, Lactation and Labeling Rule, and to update Section 13 of the PI to include information on male and female fertility.

### **LABELING**

We hereby approve the draft package insert labeling submitted under Amendment 5003, dated December 17, 2018.

### **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 103239/5606 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