



Our STN: BL 103239/5758

**SUPPLEMENT APPROVAL**

GlaxoSmithKline Biologicals  
Attention: Thomas F. Kline  
1250 South Collegeville Road  
Collegeville, PA 19426

October 27, 2023

Dear Mr. Kline:

We have approved your request received April 28, 2023, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Hepatitis B Vaccine, Recombinant (ENGERIX-B) manufactured at GSK Biologicals (Rixensart (b) (4) Belgium), at (b) (4) and at (b) (4) to update the language in the ENGERIX-B package insert and the carton labels associated with replacing the syringe type with a new 1.25-mL Luer lock, borosilicate glass, type (b) (4) syringe.

## **LABELING**

We hereby approve the draft content of labeling Package Insert submitted on October 10, 2023, and the draft carton labels submitted on April 28, 2023.

## **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, Patient Package Insert submitted on April 28, 2023. 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 carton and container labels submitted on April 28, 2023, 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 103239 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)).

We will include the information contained in the above-referenced supplement in your BLA file.

Sincerely,

For David C. Kaslow, MD  
Acting Deputy Director - Clinical  
Division of Vaccines and  
Related Products Applications  
Office of Vaccines  
Research and Review  
Center for Biologics  
Evaluation and Research