Our STN: BL 125614/1022

SUPPLEMENT APPROVAL
PMC FULFILLED
March 21, 2025

GlaxoSmithKline Biologicals
Attention: Susan Gamble, PhD
14200 Shady Grove Road
Rockville, MD 20850-7464

Dear Dr. Gamble:

We have approved your request received May 22, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Zoster Vaccine Recombinant, Adjuvanted (SHINGRIX), manufactured at the GlaxoSmithKline Biologicals, S. A. facility in (b) (4) Belgium, to update the US Prescribing Information to include information from Study Zoster-049 on long term effectiveness of SHINGRIX.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT02723773.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 13, dated March 20,2025.

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 March 20, 2025. 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 125614, 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

FULFILLED POSTMARKETING COMMITMENT

This submission fulfills your postmarketing commitment #3 identified in the October 20, 2017, approval letter for BLA STN BL 125614/0 for Zoster Vaccine Recombinant, Adjuvanted (SHINGRIX). The commitment addressed in this submission is as follows:

3. Study Zoster-049 to assess the long-term efficacy, immunogenicity and safety of SHINGRIX in adults ≥50 years of age.

   Final Protocol Submission: December 18, 2015

   Study Completion: July 28, 2023

   Final Report Submission: May 25, 2024

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

Sincerely,

R. Douglas Pratt, MD, MPH
Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research