Our STN: BL 125614/464

SUPPLEMENT APPROVAL

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

March 24, 2021

Dear Dr. Armstrong:

We have approved your request submitted and received on February 18, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Zoster Vaccine Recombinant, Adjuvanted (SHINGRIX), manufactured at your (b) (4) Belgium location, to update the "Warnings and Precautions" and "Adverse Reactions" sections of the Package Insert labeling to include new safety information on the risk of Guillain-Barré Syndrome (GBS) following vaccination with SHINGRIX.

The review of this supplement was associated with our January 22, 2021 Safety Labeling Change Notification Letter, in which we notified you, under Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA), of new safety information that we determined should be included in the labeling for SHINGRIX. This information pertains to an increased risk of GBS during the 42 days following vaccination with SHINGRIX observed in a post-marketing, observational study.

LABELING

We hereby approve the draft Package Insert labeling submitted under amendment 2, dated March 18, 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 March 18, 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 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)).

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