Our STN: BL 125614/700

SUPPLEMENT APPROVAL
May 22, 2023

GlaxoSmithKline Biologicals
Attention: Susan Gamble, Ph.D.
1400 Shady Grove Road
VR1500
Rockville, MD 20850-7464

Dear Dr. Gamble:

We have approved your request received July 22, 2022, 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 your (b) (4), Belgium location to include data on safety and the immune responses to SHINGRIX when administered concomitantly with Pneumococcal Vaccine Polyvalent (Pneumovax 23), Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM_{197} Protein) (PREVNAR 13) or Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed (BOOSTRIX), or following revaccination after vaccination with Zoster Vaccine Live (ZOSTAVAX).

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT02045836, NCT03439657, NCT02052596 and NCT02581410.

LABELING

We hereby approve the draft content of Package Insert labeling submitted under amendment 20, dated May 18, 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 submitted on May 18, 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.

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 files.

Sincerely,

Joseph G. Toerner, MD, MPH
Acting Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research