



Our STN: BL 125614/195

SUPPLEMENT APPROVAL

GlaxoSmithKline Biologicals
Attention: Norris Pyle
14200 Shady Grove Road
VR1500
Rockville, MD 20850-7464

May 17, 2019

Dear Mr. Pyle:

We have approved your request submitted on November 16, 2018, and received on November 16, 2018, 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 revise the package insert labeling to add Section 6.2 Postmarketing Experience under the Adverse Reactions section to include information regarding immune system disorders and general disorders and administration site conditions.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 1, dated May 16, 2019.

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.

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:

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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, MD, PhD
Deputy Director - Clinical
Division of Vaccines and
Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research