



Our STN: BL 125775/330

SUPPLEMENT APPROVAL

GlaxoSmithKline Biologicals
Attention: Nitisha Pyndiah, Ph.D.
14200 Shady Grove Road
Rockville, MD 20850-7464

January 6, 2025

Dear Dr. Pyndiah:

We have approved your request received on November 22, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for Respiratory Syncytial Virus Vaccine, Adjuvanted (AREXVY) manufactured at your facility in Wavre, Belgium to update the “Warnings and Precautions” and “Adverse Reactions” sections of the Package Insert to include new safety information on the risk of Guillain-Barré syndrome (GBS) following vaccination with AREXVY.

The review of this supplement was associated with our October 25, 2024, SAFETY LABELING CHANGE NOTIFICATION LETTER, notifying you, under Section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act (FDCA), of new safety information that we believe should be included in the labeling for AREXVY. This information pertains to data from a postmarketing observational study that suggest an increased risk of GBS during the 42 days following vaccination with AREXVY.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 2, dated December 19, 2024.

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 December 19, 2024. 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 125775, 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.

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

Sincerely,

Rebecca Reindel, M.D.
Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research