U.S. FOOD & DRUG ADMINISTRATION

Our STN: BL 125775/485

SUPPLEMENT APPROVAL
July 27, 2026

GlaxoSmithKline Biologicals
Attention: Joanna Warren, Ph.D.
2000 Tower Oaks Blvd
Suite 360
Rockville, MD 20852

Dear Dr. Warren:

We have approved your request received September 26, 2025, 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) to update the Package Insert to add Section 8.6 (Immunocompromised Individuals 18 Years of Age and Older), to include safety and immunogenicity data in individuals 18 years of age and older with lung or renal solid organ transplant who received either one or two doses of AREXVY.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT05921903.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 14, dated July 14, 2026.

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 July 14, 2026. 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,

Andrea Hulse, M.D.
Acting Deputy Director
Division of Clinical and Toxicology Review
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research