Our STN: BL 125775/499

SUPPLEMENT APPROVAL
April 30, 2026

GlaxoSmithKline Biologicals
Attention: Lori Gibbons
1250 South Collegeville Road
Collegeville, PA 19246

Dear Ms. Gibbons:

We have approved your request received on October 31, 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 include a vial and prefilled syringe (vial-PFS) presentation, consisting of a vial of Lyophilized Antigen Component (with the RSVPreF3 antigen overage reduced from (b) (4) and a prefilled syringe of Adjuvant Suspension Component, and associated labeling revisions.

Under this supplement, you are approved to:

1. Manufacture Final Bulk and Final Container of Lyophilized Antigen Component (with (b) (4) RSVPreF3 antigen overage) for the vial-PFS presentation of AREXVY at (b) (4) using the (b) (4) filling line and (b) (4) using the (b) (4) filling lines.

2. Manufacture PFS containing Adjuvant Suspension Component of AREXVY at (b) (4) using the (b) (4) filling lines and Final Bulk of AS01E and PFS containing Adjuvant Suspension Component of AREXVY at (b) (4) using (b) (4) filling lines.

3. Label and package the vial-PFS presentation of AREXVY at (b) (4)

The expiry dating period for each component of the vial-PFS presentation of AREXVY is 36 months from the date of filling when stored at +2ºC to +8ºC. The expiration date for the packaged vial-PFS presentation of AREXVY shall be dependent on the shortest expiration date of any component.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 18, dated April 23, 2026, the draft carton labels submitted under amendment 18, dated April 23, 2026, and the draft container labels submitted initially under STN 125775/499, dated October 31, 2025.

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 April 23, 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.

CARTON AND CONTAINER LABELS

Please electronically submit final printed carton and container labels identical to the carton and container labels submitted on April 23, 2026 and October 31, 2025, respectively, according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications* at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/providing-regulatory-submissions-electronic-format-certain-human-pharmaceutical-product-applications.

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.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We acknowledge your written commitment as described in your amendment 17, dated April 17, 2026, as outlined below:

1. To submit the final Plunger Stopper Movement Study Report (for a presentation that is representative of the vial-PFS presentation of AREXVY)

   Final Report Submission: December 15, 2026

We request that you submit the final report requested above to your BLA, STN BL 125775. Please refer to the sequential number for the commitment.

Please use the following designators to prominently label all submissions, including supplements, relating to these postmarketing study commitments as appropriate:

- **Postmarketing Commitment – Correspondence Status Update**
- **Postmarketing Commitment – Final Study Report**
- **Supplement contains Postmarketing Commitment Final Study Report**

For each postmarketing commitment not subject to the reporting requirements of 21 CFR 601.70, you may report the status to FDA as a **Postmarketing Study Commitment – Correspondence Status Update**. The status report for each commitment should include:

- the sequential number for each study as shown in this letter;
- the submission number associated with this letter;
- describe what has been accomplished to fulfill the non-section 506B PMC; and,
- summarize any data collected or issues with fulfilling the non-section 506B PMC.

When you have fulfilled your commitment, submit your final report as **Postmarketing Commitment – Final Study Report** or **Supplement contains Postmarketing Commitment Final Study Report**.

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

Sincerely,

Jerry P. Weir, PhD
Director
Division of Viral Products
Office of Vaccines Research Review
Center for Biologics Evaluation and Research