



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: April 10, 2023

TO: Santosh Nanda, Chair
Edward Wolfgang and Nikunj Sharma, RPMs CBER/OVRR/DVRPA

FROM: Oluchi Elekwachi, Regulatory Reviewer
OCBQ/DCM/APLB

THROUGH: Lisa Stockbridge, Branch Chief
OCBQ/DCM/APLB

SUBJECT: Labeling Review
AREXVY (Respiratory Syncytial Virus Vaccine Recombinant,
Adjuvanted)
STN: 125775
Sponsor: GlaxoSmithKline Biologicals

The sponsor submitted:

<input checked="" type="checkbox"/>	Original Application
<input type="checkbox"/>	Major Amendment
<input type="checkbox"/>	Prior Approval Supplement (PAS)
<input type="checkbox"/>	Changes Being Effected (CBE) Supplement

The submission contains:

<input checked="" type="checkbox"/>	Prescribing Information (PI)
<input type="checkbox"/>	Patient Package Insert (PPI)
<input checked="" type="checkbox"/>	Package and Container - labels - submitted March 13, 2023 <ul style="list-style-type: none">• Vial labels• Carton labels

BACKGROUND

On September 2, 2022, GSK submitted an original application (BLA 125775) for AREXVY (Respiratory Syncytial Virus Vaccine Recombinant, Adjuvanted). Its proposed indication is for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus RSV-A and RSV-B subtypes in adults 60 years of age and older. The vaccine is supplied as a single-dose vial of lyophilized RSVPreF3 antigen component to be reconstituted with the accompanying vial of AS01_E adjuvant suspension component. After reconstitution, a single dose of 0.5 mL contains 120 mcg of RSVPreF3 antigen adjuvanted with AS01_E. APLB has reviewed this submission from a promotion and comprehension perspective and have the following comments.

General

- Please ensure that there is white space between each major heading in HIGHLIGHTS.
- Use active voice and command language throughout the PI.
- Avoid practice of medicine statements.
- Avoid the use of vague instructional terminology (e.g., care should be taken).
- Revise the format of all subsection headers to title case lettering.
- Remove all headers and footers.

Highlights

- It is unnecessary and distracting to bullet every sentence in the HIGHLIGHTS. Reserve bulleting for sections that present more than one concept.
- Include the proprietary name in the product title. The proprietary name must be in all uppercase letters.

DOSAGE FORMS AND STRENGTHS

Information on the quantity of doses supplied belongs in section 16 HOW SUPPLIED/STORAGE AND HANDLING.

CONTRAINDICATIONS

- Where possible, specify the individual components in the product that can cause an allergic or anaphylactic reaction.

Full Prescribing Information: contents

Ensure that the CONTENTS are consistent with the FULL PRESCRIBING INFORMATION.

2 DOSAGE AND ADMINISTRATION

- Italicize headings within a subsection.
- Ensure that there is appropriate line spacing and no inadvertent gaps.
- Use command language, particularly in the preparation and administration steps.

2.2 Preparation

Figure 1.

To increase readability, delete “Cleanse both vial stoppers. Using a sterile needle and sterile syringe,” and retain the statement “Withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.”

2.3 Administration

Place the last sentence, “Discard reconstituted vaccine if not used within 4 hours.”, on a separate line of its own.

3 DOSAGE FORMS AND STRENGTHS

Move information on the vial doses to section 16 HOW SUPPLIED/STORAGE AND HANDLING.

4 CONTRAINDICATIONS

Specify the individual components of AREXVY that can elicit an anaphylactic reaction.

7 DRUG INTERACTIONS

This is not a required section. The statement “AREXVY can be given concomitantly with inactivated seasonal influenza vaccine” is not a drug interaction and can be considered promotional in nature. Delete information on reactivity of immunosuppressed persons since there is no data to report.

16 HOW SUPPLIED/STORAGE AND HANDLING

- Refrain from bolding text in the PI unless it is required.
- Organize section 16.1 by using bullets to identify each point.

LOGO

Delete the logo at the end of the PI.

CARTON AND CONTAINER LABELS

- For each antigen component vial, use the same font size and text color for the word “AREXVY” as used for the text before the word “AREXVY”.
- For both the antigen and adjuvant component vial labels, make the color of the text all one color throughout each vial label, outside of the red box, to decrease the potential for medication errors from all the different colors.

If you have any questions regarding this review, please contact Oluchi Elekwachi, Regulatory Review Officer at 240-402-8930.