Memorandum

DATE: May 11, 2023

TO: Goutam Sen, Chair
Paul Keller, Laura Montague, Vera Stupina, RPMs
CBER/OVRR/DVRPA

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

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

SUBJECT: Labeling Review
ABRYSVO (Respiratory Syncytial Virus Vaccine)
STN: 125769
Sponsor: Pfizer, Inc.

The sponsor submitted:

☒	Original Application
☐	Major Amendment
☐	Prior Approval Supplement (PAS)
☐	Changes Being Effected (CBE) Supplement

The submission contains:

☒	Prescribing Information (PI) – Submitted April 14, 2023
☐	Patient Package Insert (PPI)
☒	Package and Container - labels - submitted March 10, 2023 • Vial labels • Package labels

BACKGROUND

On September 30, 2022, Pfizer submitted an original application (BLA 125769) for ABRYSVO (Respiratory Syncytial Virus vaccine). Its proposed indication is for active immunization for the prevention of acute respiratory disease and lower respiratory tract disease (LRTD) caused by respiratory syncytial virus in individuals 60 years of age and older. The vaccine is supplied as a sterile, white, preservative-free, lyophilized powder in a single dose vial reconstituted with a prefilled syringe of sterile water diluent. 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

Include the proprietary name in the product title. The proprietary name must be in all uppercase letters and the proper name should be in lowercase letters except for proper nouns.

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.

FULL PRESCRIBING INFORMATION

2 DOSAGE AND ADMINISTRATON

- Emphasize route of administration with a bolded, sentence case phrase placed directly beneath the section heading. For example:

For intramuscular use only.

- Italicize headings within a subsection.
- Use command language, particularly in the preparation and administration steps.

2.2 Preparation for Administration

- The first graphic should be revised to present steps in the order in which they will be utilized. For instance, the vial adapter should be presented prior to the vial.
- To demonstrate that the syringe is pre-filled, a diagonal line may be added to represent a fluid line.
- Graphics bearing extra swirling arrow should be removed to decrease confusion.

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 ABRYSVO that can elicit an anaphylactic reaction.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 Storage and Handling

- Under Storage Before Reconstitution, consider the following revision to the last sentence in the first paragraph:

  Discard if the ~~carton~~ product has been frozen.

- Under Storage After Reconstitution consider bulleting the directive as follows:

  ABRYSVO should be administrated within 4 hours after reconstitution. Store the reconstituted vaccine at 15ºC to 30ºC (59ºF to 86ºF).

  - Do not store reconstituted vaccine under refrigerated conditions (2ºC to 8ºC [36 ºF to 46 ºF]).

- Do not freeze reconstituted vaccine.

LOGO

Delete or reduce the size of Pfizer the logo at the end of the PI.

PACKAGE AND CONTAINER LABELS

- For “ABRYSVO” remove rainbow circle in front of the name as it poses intervening matter and is distracting from the name.
- Harmonize the presentation of the proper name as written in the prescribing information.
- If the product contains no preservative, indicate such on the packaging. If so, detail the which preservative is used.

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