



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: May 16, 2023

TO: Taruna Khurana, Chair
Kamal Velmurugan and Diana Oram RPMs CBER/OVRR/DVRPA

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

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

SUBJECT: Labeling Review
CYFENDUS (anthrax vaccine adsorbed, adjuvanted)
STN: 125761
Sponsor: Emergent Product Development Gaithersburg Inc.

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 checked="" type="checkbox"/>	Patient Package Insert (PPI)
<input checked="" type="checkbox"/>	Package and Container - labels - submitted April 14, 2023 <ul style="list-style-type: none">• Vial labels• Carton labels

BACKGROUND

On April 20, 2022, EMERGENT submitted the final component to their rolling original application (BLA 125761) for CYFENDUS (anthrax vaccine adsorbed, adjuvanted). Its proposed indication is for post-exposure prophylaxis (PEP) of disease following suspected or confirmed exposure to *Bacillus anthracis* in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial regimen.

The vaccine is supplied in multiple-dose vials containing ten 0.5 mL doses. The proposed dosing regimen for CYFENDUS is two intramuscular doses of 0.5 mL each given two weeks apart. APLB has reviewed this submission from a promotion and comprehension perspective and have the following comments.

General

- Avoid practice of medicine statements.
- Avoid the use of vague instructional terminology (e.g., care should be taken).
- Be consistent with format of non-regulatory headings, such as sub-subheadings. Choose whether to italicize or underline.
- Other than standard units of measure, minimize the use of abbreviations and spell out an abbreviation each time it is used in a section.

HIGHLIGHTS

DOSAGE AND ADMINISTRATION

Consider revising to read: Administer two doses (0.5 mL each) intramuscularly two weeks apart (Week 0 and 2). (2)

DOSAGE FORMS AND STRENGTHS

Consider revising to read: CYFENDUS is a suspension for injection supplied in 5 mL multiple-dose vials. A single dose is 0.5 mL.

CONTRAINDICATIONS

If 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. Correct the name for subsection 6.1.

FULL PRESCRIBING INFORMATION

2 DOSAGE AND ADMINISTRATION

- Bold the administration statement directly beneath this section heading.
- To mitigate medication error when reading IM versus IV, consider removing the abbreviation and spelling out intramuscular each time it is used.
- Use command language, particularly in the preparation and administration steps.

2.3 Administration

- The directive, “Avoid foaming.” is out of context unless it is connected with the cause of foaming. Consider deleting “Avoid foaming” or revising this to: To avoid foaming, DO NOT SHAKE the vial.
- Revise the route of administration directive to read: Administer CYFENDUS vaccine intramuscularly.

3 DOSAGE FORMS AND STRENGTHS

It is not necessary to cross reference sections 11 or 16 from this section. Move information on the multiple-dose vials to section 16 HOW SUPPLIED/STORAGE AND HANDLING, and consider the following revision:

CYFENDUS vaccine is a suspension for intramuscular injection. Each dose is 0.5 mL.

4 CONTRAINDICATIONS

Specify the individual components of CYFENDUS that can elicit an anaphylactic reaction, where possible.

6 ADVERSE REACTIONS

The regulatory heading for subsection 6.1 is **6.1 Clinical Trials Experience**.

16 HOW SUPPLIED/STORAGE AND HANDLING

- Refrain from bolding text in the PI unless it is required by regulation.
- Revise sentence one to read: CYFENDUS vaccine is supplied in 5 mL multiple-dose vials, each containing ten doses of 0.5 mL each.

- Delete “Avoid foaming.”

PATIENT PACKAGE INSERT

What is CYFENDUS vaccine?

Consider revising the following below:

Bullet 1

- CYFENDUS vaccine is licensed by the FDA to protect against anthrax disease in persons 18 through 65 years of age after exposure to anthrax. It is used with certain recommended antibacterial drugs to protect people from getting anthrax.

Bullet 3

- Information on how well CYFENDUS vaccine works when given after exposure to anthrax comes from studies only in animals. It has not been studied in humans because there are not enough people who get the disease naturally, and it is not ethical to expose people to anthrax on purpose to find out how well the product works.

Bullet 4 – delete “ inclusive”

How is CYFENDUS vaccine given?

CYFENDUS vaccine is given as a shot in your ~~arm~~ muscle.

What are the possible or reasonably likely side effects of CYFENDUS vaccine?

~~Problems moving the arm~~ Stiffness in the muscle where you got the shot.

PACKAGE AND CONTAINER LABELS

- Decrease the prominence of the sponsor name so as to bring more attention to the product name.
- Remove “Avoid foaming.”
- Revise “Store at 2-8°C (36-46°F)” to “Store at 2 to 8°C (36 to 46°F)”
- Bold or capitalize “Do not freeze.”

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