NDA 207500/S-010
NDA 207501/S-008

SUPPLEMENT APPROVAL

Astellas Pharma US Inc.
Attention: Robert M. Reed
Senior Director, Regulatory Affairs
1 Astellas Way
Northbrook, IL 60062

Dear Mr. Reed:

Please refer to your supplemental new drug applications (sNDAs) dated and received June 10, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cresemba ((isavuconazonium sulfate) capsules, 186 mg (NDA 207500), and CRESEMBA (isavuconazonium sulfate) for injection, 372 mg (NDA 207501).

These Changes Being Effected supplemental new drug applications provide for revisions to the prescribing information (PI) to add information regarding anaphylactic reactions. Specifically, the following sections of the PI have been revised:

1) **HIGHLIGHTS OF PRESCRIBING INFORMATION**: under **RECENT MAJOR CHANGES** and **WARNINGS AND PRECAUTIONS.**
2) **TABLE OF CONTENTS:** Updated to align with changes to the PI.
3) **FULL PRESCRIBING INFORMATION:**
   a. **WARNINGS AND PRECAUTIONS (5)** section, **Hypersensitivity Reactions (5.3)** subsection: added detailed information regarding anaphylactic reactions, revised statement regarding severe skin reactions, and added information to provide more detail about specific actions that can be taken to respond to these reactions.
   b. **ADVERSE REACTIONS (6)** section: added **Post-Marketing Experience (6.2)** subsection.
   c. **PATIENT COUNSELING INFORMATION (17)** section: added risk information based on revisions to the **WARNINGS AND PRECAUTIONS (5)** section, **Hypersensitivity Reactions (5.3)** subsection.
   d. Minor editorial updates have been made throughout the PI.

Additionally, updates were made to the Patient Package Insert (PPI) to align with the changes made to the PI and minor editorial edits were made throughout the PPI.

APPROVAL & LABELING

We have completed our review of these applications as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Patient Package Insert), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in these supplements, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

If you have any questions, call Alison Rodgers, Regulatory Project Manager, at 301-796-0797.

Sincerely,

{See appended electronic signature page}

Dmitri Iarikov, MD, PhD
Deputy Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DMITRI IARIKOV
12/09/2021 10:44:17 AM