NDA 207500/S-006
NDA 207501/S-005

SUPPLEMENT APPROVAL
FULLFILLMENT OF POSTMARKETING REQUIREMENTS

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 June 12, 2020, received June 12, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA 207500/S-006 Cresemba (isavuconazonium sulfate) capsules, 186 mg
NDA 207501/S-005 Cresemba (isavuconazonium sulfate) for injection, 372 mg

These Prior Approval supplemental new drug applications provide updates to the following sections and subsections of the prescribing information: **WARNINGS AND PRECAUTIONS (5), Embryo-Fetal Toxicity (5.4); USE IN SPECIFIC POPULATIONS (8), Pregnancy (8.1),** and **NONCLINICAL TOXICOLOGY (13) Carcinogenesis, Mutagenesis, Impairment of Fertility** (**13.1**).

Additionally, these supplements provide for revision to the PI based on the results of postmarkeing requirements (PMRs) 2872-2 and 2872-3 listed in the NDA approval letter dated March 06, 2015. The PMRs evaluated the carcinogencity of isavuconazonium sulfate in 2 year mouse and rat carcinogenicity studies.

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 for the prescribing information, 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).

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated June 12, 2020, containing the final reports for the following postmarketing requirements listed in the March 06, 2015 approval letter:

2872-2	Conduct a two-year mouse carcinogenicity study
2872-3	Conduct a two-year rat carcinogenicity study

We have reviewed your submission and conclude that the above requirements were fulfilled.

This completes all of your postmarketing requirements and commitment acknowledged in our March 06, 2015 approval letter.

[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.

REPORTING REQUIREMENTS

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

If you have questions, call Sheel Shah, Pharm D, Regulatory Project Manager, at 240-402-3968.

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

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
05/18/2021 11:55:25 AM