DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21506/S-011
NDA 21506/S-012

SUPPLEMENT APPROVAL

Astellas Pharma US, Inc.
Attention: Jeanne Jarzabek
Associate Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015

Dear Ms. Jarzabek:

Please refer to your Supplemental New Drug Applications (sNDAs), dated November 29, 2010, and received November 30, 2010, (S-011), and dated and received February 1, 2011, (S-012), under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for MYCAMINE (micafungin sodium) for Injection, 50 mg/vial and 100 mg/vial.

We acknowledge receipt of your amendments dated May 4, 2011.

"Prior Approval" supplemental new drug application, S-011, provides for the addition of and revisions to the information on severe hepatic impairment.

"Changes Being Effected" supplemental new drug application, S-012, provides for additions to the **ADVERSE REACTIONS**, Postmarketing Adverse Reactions subsection.

These supplemental applications also provide for numerous editorial changes.

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text. This label is identical to the package insert submitted May 4, 2011.

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 http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the 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 titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, 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 MS Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes and annotate each change. To facilitate review of your submission, 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).

REPORTING REQUIREMENTS

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

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

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., MPH
Deputy Director for Safety
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE:
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SUMATHI NAMBIAR
06/08/2011