DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-506/S-008

Astellas Pharma US, Inc.
Attention: Mr. Robert M. Reed
Director, Regulatory Affairs
Three Parkway North
Deerfield, Illinois 60015-2548

Dear Mr. Reed:

Please refer to your supplemental new drug application (sNDA) dated December 21, 2006, received December 22, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for MYCAMINE® (micafungin sodium) for Injection, 50mg/vial and 100 mg/vial.

We acknowledge receipt of your submissions dated:

February 7, 2007	July 2, 2007	November 1, 2007
February 23, 2007	August 3, 2007	November 6, 2007
March 20, 2007	August 7, 2007	November 7, 2007
April 6, 2007	August 9, 2007	November 30, 2007
April 18, 2007	September 11, 2007	January 3, 2008
April 20, 2007	September 25, 2007	January 4, 2008
May 3, 2007	October 8, 2007	January 16, 2008
May 10, 2007	October 18, 2007	January 17, 2008
May 11, 2007	October 24, 2007	

This supplemental new drug application provides for the use of MYCAMINE® (micafungin sodium) for Injection for the treatment of patients with candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

As soon as possible, but no later than 14 days of the date of this letter, please submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling (text for the package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission "SPL for approved supplement NDA 21-506/S-008."

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indications in pediatric patients unless this requirement is waived, deferred, or inapplicable. We are deferring the submission of your pediatric studies under the Pediatric Research Equity Act (PREA) for the treatment of serious *Candida* infections (evaluation of the pharmacokinetics and safety of repeated dose intravenous micafungin sodium) in pediatric patients from 0 to 16 years old, until January 31, 2013, because this application is ready for approval for use in adults.

Your deferred pediatric studies required by section 505B(a) of the Food, Drug, and Cosmetic Act are required postmarketing study commitments. The status of these postmarketing studies must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Food, Drug, and Cosmetic Act. These commitments are listed below:

***Study 1*:**

The primary objective of this study will be to evaluate the pharmacokinetics and safety of repeated dose micafungin, 3.0 mg/kg/day for body weight ≥ 25 kg and 4.5 mg/kg/day for body weight < 25 kg, in pediatric patients from 2 to 16 years old. These weight-based dosing regimens of micafungin are predicted to result in micafungin exposures in children similar to that observed in adults dosed at the approved micafungin dose of 150 mg/day.

Final Report Submission: January 31, 2013.

***Study 2*:**

The primary objective of this study will be to evaluate the pharmacokinetics and safety of repeated dose 4.5 mg/kg/day micafungin in pediatric patients from ≥ 4months to < 2 years old. This proposed weight-based dosing regimen of micafungin is predicted to result in micafungin exposures in younger children similar to that observed in adults dosed at the approved micafungin dose of 150 mg/day.

Final Report Submission: January 31, 2013.

***Study 3*:**

The primary objective of this study will be to evaluate the pharmacokinetics and safety of repeated dose micafungin, 1.0 mg/kg/day for body weight ≥ 25 kg and 1.5 mg/kg/day for body weight < 25 kg in pediatric patients ≥ 4 months to 16 years old. These proposed weight-based dosing regimens of micafungin for antifungal prophylaxis are predicted to result in micafungin exposures in children similar to that observed in adults dosed at the approved micafungin dose of 50 mg/day.

Final Report Submission: January 31, 2013.

***Study 4*:**

The primary objective of this study will be to evaluate the pharmacokinetics and safety of repeated dose intravenous micafungin, 7 mg/kg/day in neonates and infants weighing ≥ 1000 grams, and 10 mg/kg/day in neonates and infants weighing < 1000 grams, to establish the appropriate dose (s) of micafungin in this age group. This study must be performed and analyzed by the sponsor, and the results reviewed by the FDA prior to initiating Study 5 to ensure appropriate micafungin dose selection for that study.

Final Report Submission: January 31, 2013.

***Study 5*:**

The primary objective of this study will be to evaluate the efficacy and safety of intravenous micafungin in comparison to an appropriate comparator (e.g. amphotericin B deoxycholate) for treatment of serious *Candida* infections in neonates and infants. A sub study will be conducted to evaluate the pharmacokinetics of micafungin and the comparator in this patient population.

Final Report Submission: January 31, 2013.

Submit final study reports to this NDA. For administrative purposes, all submissions related to theses pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments."**

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Special Pathogen and Transplant Products and two copies of both the promotional materials and the package insert directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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, please call Christina H. Chi, PH.D., Regulatory Health Project Manager, at 301-796-1600.

Sincerely,

{See appended electronic signature page}

Renata Albrecht, M.D.
Director
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

Enclosure: Patient Package Insert.

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

/s/

Renata Albrecht

1/22/2008 05:00:57 PM