DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-506/S-004

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

Dear Mr. Reed:

Please refer to your supplemental new drug application dated February 24, 2006, received February 27, 2006 under section 505(b)/ pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Mycamine™ (micafungin sodium) for Injection, 50 mg and 100 mg.

This supplemental new drug application provides for the addition of a 100 mg drug product formulation.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and must be formatted in accordance with the requirements of 21 CFR 201.66.

The electronic labeling rule published December 11, 2003 (FR 69009) requires submission of content of labeling [21 CFR 201.100(d)(3)] in electronic format effective June 8, 2004. For additional information, consult the guidance for industry *Providing Regulatory Submissions in Electronic Format - Content of Labeling* (April 2005). The guidance specifies that, as of fall 2005, content of labeling is to be submitted in structured product labeling (SPL) format. To facilitate our review of your submission, we ask that labeling also be submitted in MS Word format with proposed revisions clearly indicated. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-506/S-004.**" Approval of this submission by FDA is not required before the labeling is used.

In addition, we request that you submit four copies of the introductory promotional materials 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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Jacquelyn Smith, M.A., Regulatory 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: 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/

Leonard Sacks
6/27/2006 02:18:43 PM
for Dr. R. Albrecht