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APPLICATION NUMBER:

21-754

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-506
NDA 21-754

Fujisawa Healthcare, Inc.
Attention: Mr. Robert M. Reed
Associate Director, Regulatory Affairs
Three Parkway North
Deerfield, IL 60015-2548

Dear Mr. Reed:

Please refer to your new drug application (NDA) dated April 29, 2002, received April 29, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mycamine™ (micafungin sodium) for Injection, 50 mg, NDA 21-506. The August 24, 2004 submission, received August 25, 2004, constituted a complete response to our January 29, 2003 approvable letter.

We acknowledge receipt of your submissions to NDA 21-506 dated:

October 1, 2004	December 23, 2004	February 9, 2005
October 15, 2004	January 6, 2005	February 11, 2005
October 20, 2004	January 10, 2005 (2)	February 15, 2005
October 25, 2004	January 26, 2005	February 28, 2005
October 29, 2004	January 27, 2005	March 8, 2005
November 12, 2004	February 2, 2005	March 9, 2005
December 1, 2004	February 3, 2005	March 10, 2005 (2)
December 22, 2004	February 4, 2005 (2)	

We also refer to your new drug application dated April 23, 2004, received April 26, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Mycamine™ (micafungin sodium) for Injection, 50 mg, NDA 21-754.

We acknowledge receipt of your submissions to NDA 21-754 dated:

May 11, 2004	December 22, 2004	February 4, 2005 (2)
August 24, 2004	December 23, 2004	February 11, 2005
September 22, 2004	January 6, 2005	February 18, 2005
October 1, 2004	January 10, 2005 (3)	February 22, 2005
October 20, 2004	January 26, 2005	February 28, 2005
November 12, 2004	January 27, 2005	March 8, 2005
November 18, 2004	February 2, 2005	March 9, 2005
December 1, 2004	February 3, 2005	March 10, 2005 (2)

These new drug applications provide for the use of Mycamine™ (micafungin sodium) for Injection, for prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation (NDA 21-506) and for the treatment of esophageal candidiasis (NDA 21-754).

We completed our review of these applications, as amended. They are 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, immediate container and carton labels). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate these submissions “**FPL for approved NDAs 21-506 and 21-754.**” Approval of these submissions by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring the pediatric study requirement for ages 0 to 16 years for prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation and for the treatment of esophageal candidiasis.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the prophylaxis of *Candida* infections in patients ages 0 to 16 years old undergoing hematopoietic stem cell transplantation,
2. Deferred pediatric study under PREA for the treatment of esophageal candidiasis in patients ages 0 to 16 years old.

Final Report Submissions: March 30, 2010

Submit final study reports to NDA 21-506 only. For administrative purposes, all submissions related to these 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 Immunologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising,
and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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

All 15-day alert reports, periodic (including quarterly) adverse drug experience reports, field alerts, annual reports, supplements, and other submissions should be addressed to the original NDA 21-506 for this drug product, not to NDA 21-754. In the future, do not make submissions to NDA 21-754 except for the final printed labeling requested above.

The MedWatch-to-Manufacturer Program provides manufacturers with copies of serious adverse event reports that are received directly by the FDA. New molecular entities and important new biologics qualify for inclusion for three years after approval. Your firm is eligible to receive copies of reports for this product. To participate in the program, please see the enrollment instructions and program description details at www.fda.gov/medwatch/report/mmp.htm.

If you have any questions, please call Christina H. Chi, Ph.D., Regulatory Health Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

Mark J. Goldberger, M.D., M.P.H.
Director
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

Enclosure:

1. text for the package insert,
2. immediate container
3. carton labels

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

/s/

Edward Cox
3/16/05 12:54:49 PM
for Mark J. Goldberger, MD MPH