CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

50-740/SE8-001

APPROVAL LETTER

NDA 50-740/S-001

JAN 2 8 2000

Robert Reed
Fujisawa Healthcare, Incorporated
Parkway North Center
Three Parkway North
Deerfield, Illinois 60015-2548

Dear Mr. Reed:

Please refer to your supplemental new drug application dated March 26, 1999, received March 29, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AmBisome® (amphotericin B) liposome for injection, 50 mg vial. We note that this application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated May 7, May 12, and October 26, 1999, as well as January 20 and January 28, 2000.

This supplemental new drug application provides for changes to the **CLINICAL STUDIES** section, the **Pediatric Use** subsection, and the **ADVERSE REACTIONS** section to add safety results from a comparative study conducted with Abelcet® (amphotericin B lipid complex).

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the package insert submitted January 28, 2000. 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 20 copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplemental NDA 50-740/S-001." Approval of this submission by FDA is not required before the labeling is used.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to this division 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, Maryland 20857

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Practitioner" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, contact Matthew A. Bacho, Regulatory Project Manager, at (301) 827-2127.

Sincerely yours,

/S/

Mark J. Goldberger, M.D., M.P.H.
Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Evaluation IV
Center for Drug Evaluation and Research