

NDA 50-740/S-002

Fujisawa Healthcare, Inc.
Attention: Mr. Robert M. Reed
Assistant Director, Regulatory Affairs
3 Parkway North Center
Deerfield, IL 60014

Dear Mr. Reed:

Please refer to your supplemental new drug application dated July 6, 1999, received July 7, 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 as follows.

September 1, 1999	October 19, 1999	June 6, 2000
October 1, 1999	April 28, 2000	June 15, 2000
October 15, 1999	May 26, 2000	

This supplemental new drug application provides for the use of AmBisome[®] (amphotericin B) liposome for injection, for treatment of cryptococcal meningitis in HIV infected patients.

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 submitted June 15, 2000. Accordingly, the application is approved effective on the date of this letter. The final printed labeling (FPL) must be identical to the draft package insert submitted June 15, 2000.

Please submit 20 copies of the FPL as soon as they are available, in no case more than 30 days after they are 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-002." Approval of this submission by FDA is not required before the labeling is used.

We acknowledge receipt of your submissions dated June 21, 1999 (submitted to IND [] for Phase 4 Commitments 1 and 2) and July 6, 1999 (submitted to NDA 50-740 for Phase 4 Commitment 3), regarding the following Phase 4 Commitments listed in the August 11, 1997 AmBisome[®] approval letter:

1. Completion of study 96-0-021 in pediatric patients evaluating the maximum tolerated dose of AmBisome[®]. Projected completion: 2nd qtr '98.
2. Completion of study 96-0-017 in adult patients evaluating the maximum tolerated dose of AmBisome[®]. Projected completion: 1st qtr '98.
3. Completion of study 94-0-013 evaluating AmBisome[®] in the treatment of cryptococcal meningitis. Projected completion: 2nd qtr '99.

We have completed review of your Phase 4 data and conclude that the above commitments have been fulfilled.

Be advised that, as of April 1, 1999, 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 (63 FR 66632). We note that you have fulfilled the pediatric study requirement at this time.

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-40
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, call Leo Chan, Regulatory Project Manager, at (301) 827-2127.

Sincerely,

Renata Albrecht, M.D.
Acting Director
Division of Special Pathogen and
Immunologic Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research