DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-740/S-014

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

Dear Mr. Reed:

Please refer to your supplemental new drug application dated March 14, 2003, received March 17, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Am**B**isome® (amphotericin B) liposome for Injection, 50 mg/vial.

We acknowledge the receipt of your submission dated August 12, 2003.

This supplemental application submitted as "Supplement - Changes Being Effected" provides for the following revisions to the package insert (additions are double underlined and deletions are ~~strikethrough~~):

1. **STORAGE OF AMBISOME:**

   Unopened vials of lyophilized material ~~must be stored under refrigeration at 2? 8? C (36? 46? F).~~ are to be stored at temperatures up to 25° C (77° F).

2. **HOW SUPPLIED:**

   Am**B**isome for Injection is available as single ~~50 mg vial~~ cartons (equivalent to 50mg amphotericin B) and in packs of ten individual vial cartons (NDC 0469-3051-30).

3. Through out the label all terminal zeros (e.g., "1.0") have been deleted.

We have completed the review of this supplemental application 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 (enclosed). Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling (text for the package insert submitted March 14, 2003).

Please submit copies of the final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Please submit a Microsoft Word version of the FPL in the same submission with the PDF version. 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. Please individually mount ten of the copies on heavyweight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 50-740/S-014." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" 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, please call Christine Lincoln, RN, M.S., MBA, Labeling Reviewer, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

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

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

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