

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
50-740/SE1-002

CORRESPONDENCE

NDA 50-740/S-002

JUL 16 1999

Fujisawa Healthcare, Inc.
3 Parkway North Center
3rd Floor
Deerfield, IL 60015

Attention: Robert M. Reed
Assistant Director,
Regulatory Affairs

Dear Mr. Reed:

We acknowledge receipt of your supplemental application for the following:

Name of Drug: AmBisome (amphotericin B) liposome for injection

NDA Number: 50-740

Supplement Number: S-002

Date of Supplement: July 6, 1999

Date of Receipt: July 7, 1999

Unless we find the application not acceptable for filing, this application will be filed under Section 505(b)(1) of the Act on September 5, 1999 in accordance with 21 CFR 314.101(a).

All communications concerning this NDA should be addressed as follows:

Food and Drug Administration
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research
Attention: Document Control Room
5600 Fishers Lane
Rockville, MD 20857

Sincerely,

/s/
Ellen C. Frank, R.Ph.
Chief, Project Management Staff
Division of Special Pathogen and
Immunologic Drug Products, HFD-590
Office of Drug Evaluation IV
Center for Drug Evaluation and Research