



NDA 50-740/S-016

Astellas Pharma US, Inc.  
Attention: Robert Reed  
Director, Regulatory Affairs  
Three Parkway North  
Deerfield IL, 60015-2548

Dear Mr. Reed:

Please refer to your supplemental new drug application dated April 7, 2008, received April 8, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AmBisome<sup>®</sup> (amphotericin B) Liposome for Injection.

We acknowledge receipt of your submissions dated July 22, and October 7, 2008.

This supplemental new drug application provides for the following changes to the package insert, as well as various editorial changes (additions are noted by underline and deletions are noted by ~~strikethrough~~):

1. In the **ADVERSE REACTIONS/Less Common Adverse Events** subsection, the paragraph before the **Clinical Laboratory Values** subsection is modified as follows:

The following infrequent adverse experiences have been reported in post-is marketing surveillance, in addition to those mentioned above: angioedema, erythema, urticaria, bronchospasm, cyanosis/hypoventilation, pulmonary edema, agranulocytosis, hemorrhagic cystitis.

2. In the **OVERDOSAGE/Management** subsection, a new sentence is added as follows:

If overdose should occur, cease administration immediately. Symptomatic supportive measures should be instituted. Particular attention should be given to monitoring renal function. Hemodialysis or peritoneal dialysis do not appear to significantly affect the elimination of AmBisome.

We completed our review of this application as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text submitted on October 7, 2008.

Within 21 days of the date of this letter, submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions “**SPL for approved supplement NDA 50-740/S-016.**”

If you issue a letter communicating important information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH  
Food and Drug Administration  
Suite 12B05  
5600 Fishers Lane  
Rockville, MD 20857

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

If you have any questions, call Sherry Spriggs, Regulatory Project Manager, at (301) 796-4018.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure: Package Insert

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Renata Albrecht  
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