DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-227/S-028 **SUPPLEMENT APPROVAL**

Merck Research Laboratories
Attention: Chitrananda Abeygunawardana, Ph.D.
Associate Director, Regulatory Affairs
PO Box 1000
UG2D-068
North Wales PA 19454

Dear Dr. Abeygunawardana:

Please refer to your supplemental new drug application (sNDA) dated and received July 9, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for CANCIDAS (caspofungin acetate) for Injection, 50mg/vial and 70 mg/vial.

We also refer to your submission dated September 9, 2010, containing Final Printed Labeling (FPL) for this supplemental application.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the package insert (additions are reflected as underlined text):

1. In the FULL PRESCRIBING INFORMATION: CONTENTS*, under 6 ADVERSE REACTIONS, the section 6.2 is modified to read as follows

   6.2 Clinical Trials Experience in Pediatric Patients (3 months to 17 years of age)

2. In the FULL PRESCRIBING INFORMATION, under 6 ADVERSE REACTIONS, 3rd paragraph, the word "angioedema" is added as follows:

   Anaphylaxis has been reported during administration of CANCIDAS. Possible histamine-mediated symptoms have been reported including reports of rash, facial swelling, angioedema, pruritus, sensation of warmth, or bronchospasm.

We also note that your proposed labeling contains several editorial corrections that do not require our approval.

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your September 9, 2010, submission includes final printed labeling (FPL) for your package insert. We have not reviewed this FPL. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 Judit Milstein, Chief, Project Management Staff, at (301) 796-0763.

Sincerely,

{See appended electronic signature page}

Ozlem Belen, MD, MPH
Deputy Director for Safety
Division of Special Pathogen and Transplant Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

OZLEM A BELEN
10/22/2010