DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-227/S-024

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 November 7, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cancidas™ (caspofungin acetate) for Injection, 50 mg/vial and 70 mg/vial.

We acknowledge receipt of your submission dated April 23, 2009.

This supplemental new drug application provides for the following revisions to the text of the carton and immediate container labels:

CARTON LABEL for the 50 mg product

Statement that reads "Once reconstituted with 10.8 mL of diluent each mL contains 5 mg" is replaced with "Reconstitute with 10.8 mL of diluent to obtain a concentration of 5 mg/mL."

CARTON LABEL for the 70 mg product

Statement that reads "Once reconstituted with 10.8 mL of diluent each mL contains 7 mg" is replaced with "Reconstitute with 10.8 mL of diluent to obtain a concentration of 7 mg/mL."

IMMEDIATE CONTAINER LABEL for the 50 mg product

Statement that reads "For instructions on reconstitution and dilution and dosage, see Package Insert" is replaced with "Reconstitute with 10.8 mL of diluent to obtain a concentration of 5 mg/mL."

IMMEDIATE CONTAINER LABEL for the 70 mg product

Statement that reads "For instructions on reconstitution and dilution and dosage, see Package Insert" is replaced with "Reconstitute with 10.8 mL of diluent to obtain a concentration of 7 mg/mL."

We also note that this submission contains several editorial revisions such as changes in font, spacing between sections, addition of established name and color band.

We completed our review of this supplemental application as amended. This supplemental application is approved, effective on the date of this letter, for use as recommended in the enclosed labels for the carton and immediate container.

Submit final printed carton and container labels that are identical to the enclosed carton and container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format-Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* For administrative purposes, designate this submission as **"Final Printed Carton and Container Labels for approved NDA 21-227/S-024."** Approval of this submission by FDA is not required before the labeling is used. Marketing of the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved drug.

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, please call Christina H. Chi, Ph.D., Regulatory Health Project Manager, at (301) 796-1600.

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: carton and immediate container labels

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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