DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-227/S-012

Merck & Co., Inc
Attention: Tamra L. Goodrow, Ph.D.
Director, Regulatory Affairs
Sumneytown Pike, P.O. Box 4, BLA-20
West Point, PA 19486-0004

Dear Dr. Goodrow:

Please refer to your supplemental new drug application dated September 8, 2003, received September 9, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cancidas (caspofungin acetate) for Injection.

We acknowledge receipt of your submissions dated below:

February 12, 2004	May 11, 2004	June 14, 2004	August 18, 2004
February 27, 2004	May 18, 2004	June 17, 2004	August 19, 2004
March 15, 2004	May 19, 2004	June 30, 2004	August 20, 2004
March 16, 2004	May 20, 2004	July 1, 2004	September 2, 2004
March 24, 2004	May 21, 2004	July 15, 2004	September 17, 2004
April 29, 2004	May 25, 2004	July 16, 2004	September 27, 2004
May 7, 2004	June 10, 2004	July 23, 2004	September 28, 2004

This supplemental new drug application provides for the use of Cancidas (caspofungin acetate) for Injection for empirical therapy of presumed fungal infections in febrile, neutropenic patients (ETFN).

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted September 28, 2004). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and Providing *Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted

in paper. For administrative purposes, designate this submission "**FPL for approved NDA 21-227/S-012**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are deferring submission of your pediatric studies for this new indication for ages 0 to 16 years old until September 30, 2009.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The status of this postmarketing study shall be reported annually according to 21 CFR 314.81. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of presumed fungal infections in febrile, neutropenic patients in pediatric patients ages 0 to 16 years old.

   Final Report Submission: September 30, 2009.

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated **"Required Pediatric Study Commitments"**.

In addition, submit three copies of the introductory promotional materials that you propose to use for this new indication. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the reviewing Division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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, HF-2
FDA
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 Project Manager, at (301) 827-2127.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert

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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