DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-227/S-001
NDA 21-227/S-003

Merck Research Laboratories
Attention: Tamra Goodrow, Ph.D.
Director, Regulatory Affairs
P.O. Box 4
West Point, PA 19486

Dear Dr. Goodrow:

Please refer to your supplemental new drug application (S-001) dated May 7, 2001, received May 8, 2001, submitted under section 505(b) pursuant to the Federal Food, Drug, and Cosmetic Act for Cancidas® (caspofungin acetate) For Injection.

We acknowledge receipt of your submissions dated below:

March 8, 2002	March 11, 2002	March 12, 2002
March 13, 2002	September 6, 2002	September 10, 2002
September 11, 2002 (2)	September 12, 2002	September 13, 2002
September 19, 2002	September 20, 2002 (2)	

Your submission of March 27, 2002, constituted a complete response to our March 7, 2002, action letter.

This supplemental new drug application (S-001) provides for the use of Cancidas® (caspofungin acetate) For Injection for the treatment of esophageal candidiasis.

We also acknowledge your supplemental new drug application (S-003) dated October 31, 2001, received November 2, 2001, submitted under section 505(b) pursuant to the Federal Food, Drug, and Cosmetic Act for Cancidas® (caspofungin acetate) For Injection.

We acknowledge receipt of your submission dated March 8, 2002.

This supplemental new drug application (S-003) provides for changes to the **PRECAUTIONS: Drug Interactions** subsection and the **DOSAGE AND ADMINISTRATION** section of the package insert.

We have completed our review of these applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective as recommended in the agreed upon labeling text. These applications are approved effective of the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert submitted September 19, 2002).

Please submit the FPL electronically according to the Guidance for Industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplements of NDA 21-227/S-001 and S-003". Approval of this submission by FDA is not required before the labeling is used.

Be advised that, as of April 1999, 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 (63 *FR* 66632). We note that you have not fulfilled the requirements of 21 CFR 314.55 (or 601.27). We are deferring submission of your pediatric studies for this indication until January 28, 2006.

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 this 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 (301) 827-2127.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Marked-Up 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
9/20/02 05:05:48 PM
NDA 21-227/S-001 and S-003