DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21227/S-029

SUPPLEMENT APPROVAL

Merck Sharp & Dohme Corp.
Attention: Barbara Gunther, MA, MBA
Associate Director, Global Regulatory Affairs
2015 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Gunther:

Please refer to your Supplemental New Drug Application (sNDA) dated October 5, 2011, received October 5, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cancidas (caspofungin acetate).

This "Changes Being Effected" supplemental new drug application provides Final Printed Labeling for the 70 mg carton. The revised carton labeling corrects a discrepancy between the recommended maximum final concentration listed on the Cancidas 70 mg product carton and the recommended maximum final concentration listed in the package insert.

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

CARTON LABEL

We acknowledge your October 5, 2011, submission containing a final printed carton label.

REPORTING REQUIREMENTS

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 Alison Rodgers, Regulatory Project Manager, at (301) 796-0797.

Sincerely,

{See appended electronic signature page}

John Farley, MD, MPH
Acting Director
Division of Anti-Infective Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

ENCLOSURE: Carton

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

/s/

JOHN J FARLEY
04/30/2012