DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-337/S-028

Merck & Co., Inc.
Attention: Robert A. Fromtling, Ph.D.
Director, Regulatory Affairs
P.O. Box 2000, RY 33-212
Rahway, NJ 07065-0900

Dear Dr. Fromtling:

Please refer to your supplemental new drug application dated April 25, 2007, received April 26, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (ertapenem sodium).

We acknowledge receipt of your submissions dated June 4 and December 11, 2007, February 15 and March 18, 2008. Your submission of February 15, 2008 constituted a complete response to our November 16, 2007 action letter.

This "Changes Being Effected" supplemental new drug application revises the WARNINGS, Seizure Potential section, and PRECAUTIONS, Drug Interactions section to include text regarding decreased serum levels of valproic acid with co-administration of ertapenem.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format submitted on March 18, 2008.

We note that your March 18, 2008 submission includes final printed labeling (FPL) for your package insert. 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.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to the NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Susmita Samanta, MD, Regulatory Project Manager, at (301) 796-1400.

Sincerely,

{See appended electronic signature page}

Katherine A. Laessig, M.D.
Deputy Director
Division of Anti-Infective and Ophthalmology Products
Office of Antimicrobial Products
Center for Drug Evaluation and Research

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

/s/

Kathrine Laessig
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