



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

NDA 21-337/S-033

**SUPPLEMENT APPROVAL**

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 August 12, 2009, received September 1, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (ertapenem).

This "Changes Being Effected" supplemental new drug application provides for revisions to the **WARNINGS** and **PRECAUTIONS** sections to include valproic acid interaction information.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, submitted on August 31, 2009.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at <http://www.fda.gov/oc/datacouncil/spl.html> that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "**SPL for approved NDA 21-337/S-033.**"

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please contact Susmita Samanta, M.D., Regulatory Project Manager, at 301-796-0803.

Sincerely,

*{See appended electronic signature page}*

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

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21337	SUPPL-33	MERCK AND CO INC	INVANZ (ERTAPENEM SODIUM)

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

/s/

KATHERINE A LAESSIG  
10/06/2009