



NDA 21-337/S-014

Merck & Co., Inc.  
Attention: Sandra J. Rattray, Ph.D.  
Associate Director, Regulatory Affairs  
P.O. Box 2000, RY 33-200  
Rahway, NJ 07065-0900

Dear Dr. Rattray:

Please refer to your supplemental new drug application dated November 25, 2003, received November 26, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (Ertapenem Sodium).

This “Changes Being Effected” supplemental new drug application provides for revised labeling to comply with the FDA’s Final Rule entitled “Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use (21 CFR Part 201)”, published on February 6, 2003 (68 FR 6062).

We completed our review of this supplemental application and it is approved, effective on the date of this letter.

The final printed labeling (FPL) must be identical to the labeling submitted November 25, 2003 (package insert #9500002). This label should also include the addition to the “Post-Marketing Experience” subsection of the ADVERSE REACTIONS section approved on April 30, 2004 under Supplement #013.

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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-337/S-014." Approval of this submission by FDA is not required before the labeling is used.

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, HFD-410  
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, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

*{See appended electronic signature page}*

Janice M. Soreth, M.D.  
Director  
Division of Anti-Infective Drug Products (HFD-520)  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

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/s/

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Janice Soreth

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