



NDA 21-337/S-015

Merck & Co., Inc.  
Attention: Sandra J. Rattray, Ph.D.  
Director, Regulatory Affairs  
P.O. Box 2000  
RY 32-605  
Rahway, New Jersey 07065-0900

Dear Dr. Rattray:

Please refer to your supplemental new drug application dated March 12, 2004, received March 15, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (Ertapenem for Injection).

This supplemental new drug application provides for the addition of the following microorganisms in the **CLINICAL PHARMACOLOGY** section, Microbiology subsection: *Staphylococcus epidermidis* (methicillin susceptible strains only), *Providencia rettgeri*, *Providencia stuartii*, and *Bacteroides vulgatus*.

We completed the review of this supplemental application and it is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

Please submit the copies of final printed labeling (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 supplement NDA 21-337/S-015". Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, 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 the requirements for an approved NDA set forth under

NDA 21-337/S-015

Page 2

21 CFR 314.80 and 314.81.

If you have any questions, call Susmita Samanta, M.D., 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

Office of Drug Evaluation IV

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/

-----  
Janice Soreth

9/10/04 02:05:54 PM