



NDA 21-337/S-019

Merck & Co., Inc.  
Attention: Jeffrey R. Tucker, MD  
Director, Regulatory Affairs  
Sumneytown Pike  
P.O. Box 4, BLA-20  
West Point, PA 19486

Dear Dr. Tucker:

Please refer to your supplemental new drug application dated December 17, 2004, received December 17, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ<sup>®</sup> (Ertapenem Sodium).

We acknowledge receipt of your submissions dated January 18, February 8 and 23, March 30, April 15, June 9, July 8 and 19, August 8 and 23, September 1 and 27, and October 12, 2005.

This supplemental new drug application provides for the use of INVANZ<sup>®</sup> (Ertapenem Sodium) in the treatment of adult diabetic foot infections without osteomyelitis.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-337/S-019.**" Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

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

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Janice Soreth  
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