DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 21-337/S-017

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 July 7, 2004, received July 8, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for INVANZ™ (Ertapenem Sodium) Injection, 1 gm.

This supplemental new drug application provides for revised vial and tray labels to include new branding (checkmark logo), the barcode, the net quantity of ertapenem in each vial, and the specific number of doses per vial and tray.

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

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-017". 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 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}

James D.Vidra, Ph.D.
Chemistry Team Leader for the
Division of Anti-Infective Drug Products (HFD-520)
DNDC III, Office of New Drug Chemistry
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/

Jim Vidra

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