



NDA 50-630/S-027

Merck & Co., Inc.
Attention: Peter Kusma
Manager, Regulatory Affairs
P.O. Box 1000, UG2CD-48
North Wales, PA 19454-1099

Dear Mr. Kusma:

Please refer to your supplemental new drug application dated September 29, 2006, received October 2, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primaxin[®] I.M. Injectable Suspension (Imipenem and Cilastatin). This application is subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

This supplemental application, submitted as "Supplement - Changes Being Effected" proposes the following changes:

- In the WARNINGS section, added text regarding CNS side effects based on post marketing reports
- In the PRECAUTIONS section, revised text for consistency with the new text added under WARNINGS, and deleted "confusional state"
- In the ADVERSE REACTIONS section, added "seizures"

We completed our review of this supplemental new drug application. 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.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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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, 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

Attachment

**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
3/22/2007 03:19:08 PM