DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-587/S-064
NDA 50-630/S-026

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

Dear Ms. Wigley:

Please refer to your supplemental new drug applications dated December 7, 2005, received December 8, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primaxin™ I.V. for Injection (Imipenem and Cilastatin) (NDA 50-587), and Primaxin®I.M. Injectable Suspension (Imipenem and Cilastatin) (NDA 50-630). These applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

We acknowledge receipt of your submissions dated February 23, and June 30, 2006.

These "Changes Being Effected" supplemental new drug applications provide for the following changes:

- Acronym definition for "COPD" added as "chronic obstructive pulmonary disease" to the *Lower respiratory tract infections* subsection of the INDICATIONS AND USAGE section of the Primaxin® I.M. Injectable Suspension label (50-630).

- Added "(including fulminant hepatitis)" to the *Systemic Adverse Reactions, Gastrointestinal* subsection of the ADVERSE REACTIONS section of the Primaxin® I.V. for Injection (NDA 50-587) and Primaxin® I.M. Injectable Suspension (50-630) labels.

Additionally, as discussed and agreed to in the submission of June 30, 2006, "hepatic failure" has been added after the words "(including fulminant hepatitis)" to the *Systemic Adverse Reactions, Gastrointestinal* subsection of the ADVERSE REACTIONS section.

We have completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, dated June 30, 2006.

Submit content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical to the submitted labeling text dated June 30, 2006. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

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

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

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Wiley Chambers
8/4/2006 07:58:18 AM
Wiley Chambers signing for Janice Soreth