DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 50-587/S-072
NDA 50-630/S-035

APPROVAL LETTER

Merck & Co., Inc.
Attention: Lori Tucker Exley
Manager, Worldwide Regulatory Affairs
P.O. Box 1000, UG2C-50
North Wales, PA 19454-1009

Dear Ms. Exley:

Please refer to your supplemental new drug applications dated August 12, 2009, received August 12, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PRIMAXIN™ IV for Injection (Imipenem and Cilastatin) (NDA 50-587), and PRIMAXIN™ IM Injectable Suspension (Imipenem and Cilastatin) (NDA 50-630).

These "Changes Being Effected" supplemental new drug applications provide for revised **WARNINGS** and **PRECAUTIONS** sections to include valproic acid interaction information.

Also, for NDA 50-587, **PREPARATION OF SOLUTION, COMPATIBILITY AND STABILITY,** and **HOW SUPPLIED** sections have been updated to delete mention of the MONOVIAL® configuration, which has been discontinued.

We have completed our review of these applications. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, submitted on August 12, 2009.

To facilitate the transmission of labeling to the National Library of Medicine for public dissemination, please resubmit the enclosed content of labeling in SPL format as soon as possible, but no later than 14 days from the date of this letter. For administrative purposes, please designate this submission, "**SPL for approved NDA 50-587/S-072, NDA 50-630/S-035**."

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
Suite 12B05
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, please contact Susmita Samanta, M.D., Regulatory Project Manager, at 301-796-0803.

Sincerely,

{See appended electronic signature page}

Sumathi Nambiar, M.D., M.P.H.
Deputy Director for Safety
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/

SUMATHI NAMBIAR
08/26/2009