DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-587/S-061
NDA 50-630/S-023

Merck & Co., Inc.
Attention: Virginia G. Snyder
Associate Director, Regulatory Affairs
BLA-20
P.O. Box 4
West Point, PA 19486

Dear Ms. Snyder:

Please refer to your supplemental new drug applications dated November 25, 2003, received November 26, 2003, 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 (Imipenem and Cilastatin) [NDA 50-630]. We note that these applications are subject to the exemption provisions contained in section 125(d)(2) of Title I of the FDA Modernization Act of 1997.

These "Changes Being Effected" supplemental new drug applications provide for revised labeling to comply with the FDA's Final Rule entitled "Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use (21 CFR Part 201)", published on February 6, 2003 (68 FR 6062).

We completed our review of these supplemental applications and they are approved, effective on the date of this letter.

The final printed labeling (FPLs) must be identical to the labeling submitted November 25, 2003 (package inserts #7882128 [IV] and #7632911 [IM]).

Please submit the 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 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 50-587S-061 and NDA 50-630/S-023." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about these drug products (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to these NDA's 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 approved NDA's (21 CFR 314.80 and 314.81).

If you have any questions, call Maureen Dillon-Parker, Regulatory Project Manager, at (301) 827-2125.

Sincerely,

{See appended electronic signature page}

Janice M. Soreth, M.D.
Director
Division of Anti-Infective Drug Products (HFD-520)
Office of Drug Evaluation IV
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/

Janice Soreth

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