DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 50-587/SE5-048

Merck & Company, Inc.
Attention: Charles L. Hyman, M.D.
Director, Regulatory Affairs
P. O. Box 4
West Point, PA 19486

APR 8 1998

Dear Dr. Hyman:

Please refer to your supplemental new drug application dated April 7, 1997, received April 8, 1997, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Primaxin® I.V. (imipenem and cilastatin for injection).

We note that this application is 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 submission dated February 12, 1998. The User Fee goal date for this application is April 8, 1998.

The supplemental application provides for the treatment of serious infections caused by susceptible strains of designated microorganisms in pediatric patients.

We have completed the review of this supplemental application, including the submitted draft labeling, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the enclosed draft labeling dated April 8, 1998. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed draft labeling dated April 8, 1998.

Please submit 20 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 "FINAL PRINTED LABELING" for approved supplemental NDA 50-587/SE5-048. Approval of this submission by FDA is not required before the labeling is used.

Should additional information relating to the safety and effectiveness of the drug become available, revision of that labeling may be required.

In addition, we request that you submit a labeling supplement, as soon as possible, to provide for the following package insert revisions:

1. The microbiology subsection should be revised in accordance with the 1993 letter to ALL NDA Holders.

2. The NCCLS References should be updated.

Please submit three copies of the introductory promotional material that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please submit one copy to this Division and two copies of both the promotional material and the package insert directly to:

Food and Drug Administration
Division of Drug Marketing, Advertising and Communications,
HFD-40
5600 Fishers Lane
Rockville, Maryland 20857

Should a letter communicating important information about this drug product (i.e., a "Dear Doctor" letter) be 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 20852-9787

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 Ms. Frances V. LeSane, Regulatory Health Project Manager, at (301) 827-2125.

Sincerely yours,

Gary K. Chikami, M.D.
Director
Division of Anti-Infective Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE