DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-462/S-034
NDA 19-510/S-031
NDA 20-249/S-013

Merck & Co., Inc.
Attention: Kenneth Kramer
Associate Director
Regulatory Affairs
P.O. Box 1000, UG2CD-48
North Wales, PA 19454-1099

Dear Mr. Kramer:

Please refer to your supplemental new drug applications dated December 8, 2006, received December 11, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PEPCID Tablets (famotidine), PEPCID Injection (famotidine), and PEPCID Injection Premixed (famotidine).

We acknowledge receipt of your submissions dated December 8, 2006.

These "Changes Being Effected" supplemental new drug applications provide for the addition of convulsions in patients with impaired renal function, interstitial pneumonia, and Stevens-Johnson syndrome under the ADVERSE REACTIONS section and updates to the OVERDOSE section of the package insert.

We completed our review of these applications. These applications are 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 (text for the package insert).

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We note that you have fulfilled the pediatric study requirement for this application.

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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Wes Ishihara, Regulatory Project Manager, at (301) 796-0069.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joyce Korvick

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