NDA 19-510/S-029
NDA 20-249/S-012

Merck Research Laboratories
Attention: Michelle W. Kloss, Ph.D.
BLA-20
West Point, PA 19486-0004

14 MAR 2001

Dear Dr. Kloss:

Please refer to your supplemental new drug applications dated December 20, 2001, received December 22, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following Pepcid injection products.

NDA 19-510/S-029: Pepcid™ (famotidine) Injection
NDA 20-249/S-012: Pepcid™ (famotidine) Injection Premixed

We acknowledge receipt of your submission dated March 13, 2001.

These supplemental new drug applications provide for revisions to the package insert under the "Clinical Pharmacology in Adults" section; the "Dosage Adjustment for Patients with Severe Renal Insufficiency" subsection of the DOSAGE AND ADMINISTRATION section; and the "Geriatric Use" subsection of the PRECAUTIONS section to include a statement concerning the need for dosage adjustment in patients with both moderate and severe renal impairment.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the agreed upon enclosed labeling text. Accordingly, the supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no 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 "FPL for approved supplements NDA 19-510/S-029, and NDA 20-249/S-012." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is 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 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, call Paul E. Levine, Jr., R.Ph., Regulatory Health Project Manager, at (301) 827-7310.

Sincerely,

Lilia Talarico, M.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research