DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-325/S-019

Merck & Co., Inc.
Attention: Brenda McGuire, M.S.,R.N.
Associate Director- Worldwide Regulatory Affairs
Sumneytown Pike
P.O. Box 4, BLX-29
West Point, PA 19486

Dear Ms. McGuire:

Please refer to your supplemental new drug application dated December 8, 2005, received December 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid AC (10 mg and 20 mg famotidine) tablets.

We acknowledge receipt of your submissions dated June 2 and 6, 2006.

This supplemental new drug application proposed to remove the package insert from all primary packages.

We have completed our review of this application, as amended. This application is approved for Pepcid AC (10 mg famotidine) tablets for the 30-count carton label (representative of the 6-, 12-, 18-, 60-, 90-, 110-count carton labels) and the package insert, and Pepcid AC (20 mg famotidine) tablets for the 25-count carton label (representative of the 5-, 50-, and 65-count carton label) and the package insert 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 submitted labeling:

1) Pepcid AC (10 mg famotidine) tablets for the 30-count carton label (representative of the 6-, 12-, 18-, 60-, 90-, 110-count carton labels) submitted on June 2, 2006, with agreed upon revisions submitted on June 6, 2006 and the package insert submitted on June 2, 2006.

2) Pepcid AC (20 mg famotidine) tablets for the 25-count carton label (representative of the 5-, 50-, and 65-count carton label) submitted on June 2, 2006, with agreed upon revisions submitted on June 6, 2006 and the package insert submitted on June 2, 2006.

The final printed labeling (FPL) must be formatted in accordance with the requirements of 21 CFR 201.66.

Please submit an electronic version of the FPL **for represented all stock keeping units** 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar

material. For administrative purposes, designate this submission "**FPL for approved supplement NDA** 20-325/S-019". Approval of this submission by FDA is not required before the labeling is used.

As agreed upon at our May 23, 2006 teleconference, you may continue to use current inventories of the package insert until exhausted and then implement the use of the new, revised package insert for those package units that can not accommodate the "tips for managing heartburn" information on the carton labels.

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
WO 22, Room 4447
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

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 Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription 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/

Andrea Segal
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