DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-801/S-012

Merck & Co., Inc.
Attention: Brenda McGuire, M.S., R.N.
Associate Director, Worldwide OTC Regulatory Affairs
Sumneytown Pike
P.O. Box 4, UN-D129
West Point, PA 19486

Dear Ms. McGuire:

Please refer to your supplemental new drug application dated March 23, 2007, received March 23, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid AC (10mg famotidine) chewable tablet.

We acknowledge receipt of your submission dated July 5, 2007.

This supplemental new drug application provides for a new 20 mg strength formulation with three different flavors and new labels for Pepcid AC chewable tablet for the nonprescription treatment of frequent heartburn. Per your March 23, 2007 submission, this new formulation and strength will replace the old formulation and the currently marketed 10 mg strength chewable tablet will be discontinued.

We have completed our review of this application, as amended. This application is 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 submitted labeling:

1) Pepcid AC Chewable (20 mg famotidine) tablet
    a) Carton labels with Drug Facts:
        1. 8-count carton (berries ‘n’ cream)
        2. 25-count carton (berries ‘n’ cream)
        3. 50-count carton (berries ‘n’ cream)
        4. 50x1 unit dose (sample) dispenser carton (berries ‘n’ cream)
        5. 8-count carton (cool mint)
        6. 25-count carton (cool mint)
        7. 50-count carton (cool mint)
        8. 50x1 unit dose (sample) dispenser carton (cool mint)
        9. 8-count carton (tropical fruit)
        10. 25-count carton (tropical fruit)
        11. 50-count carton (tropical fruit)

b) Immediate Container Labels
   1. 1-count sample pouch (berries ‘n’ cream)
   2. 1-count pouch (berries ‘n’ cream)
   3. 25-count bottle label (berries ‘n’ cream)
   4. 50-count bottle label (berries ‘n’ cream)
   5. 1-count sample pouch (cool mint)
   6. 1-count pouch (cool mint)
   7. 25-count bottle label (cool mint)
   8. 50-count bottle label (cool mint)
   9. 1-count pouch (tropical fruit)
   10. 25-count bottle label (tropical fruit)
   11. 50-count bottle label (tropical fruit)

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

We remind you to remove the flag “New!” from the labels and labeling six months after introduction into the marketplace.

Please submit an electronic version of the FPL 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 20-801/S-012**." Approval of this submission by FDA is not required before the labeling is used.

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 Geri Smith, Regulatory Project Manager, at (301) 796-2204.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
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/

Joel Schiffenbauer

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