



NDA 20-958/S-012

Merck Research Laboratories
Attention: Brenda McGuire, M.S., R.N.
Associate Director
Worldwide OTC 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 February 10, 2005, received February 11, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid Complete (10 mg famotidine, 800 mg calcium carbonate, 165 mg magnesium hydroxide) chewable tablets.

We acknowledge receipt of your submission dated June 15, 2005.

This supplemental new drug application proposes labeling for 15-count pouch carton, 25-count bottle label, and package insert in both English and Spanish text.

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 (package insert submitted, 15-count pouch carton label, and 25-count bottle label submitted June 15, 2005), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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 20-958/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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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 LCDR Keith Olin, Regulatory Project Manager, at (301) 301-2293.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Acting 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
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/s/

Curtis Rosebraugh
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