

CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:
NDA 20-325 / S-015

APPROVAL LETTER
with FINAL PRINTED LABELING



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-325/S-015

Merck & Co., Inc.
Attention: Brenda A. McGuire, M.S., R.N.
Associate Director, 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 November 22, 2002, received November 22, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid™AC (10 mg famotidine) Tablets.

We acknowledge receipt of your submissions dated December 13, 2002, and February 18, 24 (2), and 25, March 7 and 26, April 2, June 30, July 14 and 25, August 6, 8, and 11, and September 22 and 23, 2003.

This supplemental new drug application provides for a 20 mg nonprescription famotidine tablet.

We have completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 6, 2003.

We remind you of your postmarketing study commitment in your submission dated September 22, 2003. This commitment is listed below.

1. Conduct a clinical trial to assess the efficacy of famotidine 10 mg and 20 mg for the prevention of heartburn in non-Caucasian subjects after a provocative meal.

Protocol Submission: Within 6 months of the date of this letter
Study Start: Within 4 months of FDA agreement with the proposed study design
Final Report Submission: Within 12 months of study start (date determined according to the first subject enrolled).

Submit clinical protocols to your IND for this product. Submit all final study reports to this NDA. In addition, under 21 CFR 314.81(b)(2)(vii) and 314.81(b)(2)(viii), you should include a status summary of this commitment in your annual report to this NDA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies, number of patients entered into each study. All submissions, including supplements, relating to this postmarketing study commitment must be prominently labeled

“Postmarketing Study Protocol”, “Postmarketing Study Final Report”, or “Postmarketing Study Correspondence.”

We remind you to remove the word “NEW!” on the Principal Display Panel (PDP) after 180 days of marketing.

Consider the following revisions to be implemented at the next printing of your labeling.

1. In **Drug Facts** under *Directions*, add “Do not chew” at the end of the first sub-bulleted statement.
2. Remove the “s” from the word “tablets” in “Famotidine Tablets 20mg” on the Blister Package labeling to indicate that each blister contains 1 tablet.
3. In the package insert under **Allergy alert**, the warning “Do not use if you have kidney disease, except under the advice and supervision of a doctor” is not an allergy alert. We recommend that you distinguish this warning from the Allergy alert heading and make it more prominent.
4. In the package insert under “Proven effective in clinical studies”, revise the labeling for bar graphs C and D by including “10 minutes*” under “Study C” and “Study D” and adding in the area below the bar graphs the descriptive statement, that reads “*Time taken before eating a meal that is expected to cause symptoms”, to be consistent with the 10 mg-bar graph label.
5. In order to be consistent with the 20 mg prevention studies in which famotidine was taken 10 minutes before a provocative meal, we recommend that you revise all labeling related to the directions for prevention of heartburn to read “to **prevent** symptoms, swallow 1 tablet with a glass of water at any time from **10 to 60 minutes before** eating food or drinking beverages that cause heartburn”.

In addition, we request that you submit two copies of the introductory promotional materials you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Over-the-Counter Drug Products and one copy to the Division of Gastrointestinal and Coagulation Drug Products.

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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Laura Shay, Regulatory Project Manager, at (301) 827-2274.

Sincerely,

{See appended electronic signature page}

Charles Ganley, MD
Director
Division of Over the Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

Sincerely,

{See appended electronic signature page}

Robert Justice, MD
Director
Division of Gastrointestinal and Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research