NDA 20-801

Merck Research Laboratories
Attention: George Latyszonek
Director, Regulatory Affairs
Sumneytown Pike, BLA-20
West Point, PA 19486

Dear Mr. Latyszonek:

Please refer to your new drug application (NDA) dated December 18, 1996, received December 19, 1996, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pepcid AC (famotidine) Chewable Tablets.

We acknowledge receipt of your submissions dated August 21 and September 11 and 24, 1998. The August 21, 1998 submission, received on August 24, 1998, constituted a full response to our August 5, 1998 action letter. The user fee goal date for this application is October 24, 1998.

This new drug application provides for a chewable tablet dosage form of nonprescription Pepcid AC (famotidine) for the treatment or prevention of meal-induce heartburn, acid indigestion, and sour stomach.

We have completed the review of this application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the submitted final printed labeling (package insert and immediate container and carton labels submitted on August 21, 1998). Accordingly, the application is approved effective on the date of this letter.

We remind you of the commitment stated in your submission dated September 24, 1998, to revise the labeling for the drug product by December 7, 1998, to include the following warning:

> "**Allergy Warning**: Do not use if you are allergic to Pepcid AC (famotidine) or other acid reducers."

In addition, we remind you of the commitment made in your submission dated August 21, 1998, to revise the labeling for the drug product within six months as follows:

1. Revise the statements in the **USES** section as follows to denote heartburn as the primary symptom, with the other symptoms as secondary symptoms:

   - "For relief of heartburn associated with acid indigestion and sour stomach;"
   - "For prevention of heartburn associated with acid indigestion and sour stomach brought on by eating or drinking certain food and beverages."

   Do not bold or underline any word or statement in this section.

2. Regarding the **DIRECTIONS** section on all labeling components, bold only the following words or phrase: "**relieve"**, **"prevent"**, and "**60 minutes before"**.

3. Regarding the **WARNINGS** section on all labeling components, move the pregnancy/nursing warning statement to immediately before the "Keep this and all drugs out of reach of

4. Concerning the first and second bullet statements at the top of the back panel of the carton and pouch dispenser:

   a. Remove all underlining from these statements.

   b. To be consistent with the statement in the **READ THE LABEL** section of the label, revise the phrase "(Read Consumer Leaflet before use)" in the first bullet to "(Read Package Insert before use)." In addition, consider including the text "Package Insert" on the front panel of the package insert labeling to make it easier for consumers to identify this document.

5. Revise the third bullet statement under the "Tips for Managing Heartburn" in the labeling to: "Certain foods or drinks are more likely to cause heartburn, such as rich, spicy, fatty, and fried foods, chocolate, caffeine, alcohol, and even some fruits and vegetables."

6. Regarding the Tamper Resistant/Tamper Evident Statements:

a. On the back panel of the pouch, revise this Statement "Do not use if pouch is open or broken" by replacing the word "broken" with "torn." In addition, move this statement from the "**WARNINGS"** section to either near the diagonal phrase "While folded on line, tear open at slit" or immediately before the phrase "READ THE DIRECTIONS

b. Revise this statement, "Do not use if the individual pouch is open or broken," on the back panel of the carton and dispenser and on the front page of the package insert to read "Do not use if the individual pouch is open or torn."

c. Revise the font for all of these statements from all upper case to upper and lower case.

In addition, we request that you consider reformatting the labeling as outlined in the February 27, 1997, Federal Register Notice "Over-the-Counter Human Drugs; Proposed Labeling

Please submit 20 copies of the revised final printed labeling (FPL) as a "Special Supplement – Changes

Finally, validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued cooperation to resolve any problems that may be identified.

Please submit four copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Gastrointestinal and Coagulation Drug Products, one to the Division of Over-the-Counter Drug Products, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-40
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

In line with Center for Drug Evaluation and Research policy, oversight of this application is being transferred to the Division of Over-the-Counter Drug Products. If you have any questions, contact Albert Rothschild, Project Manager, at (301) 827-2222.

Sincerely,

Debra Bowen, M.D.
Acting Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

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