and pouches, add the following allergy warning statement: [redacted] DRAFT LABELING [redacted] In addition, this warning statement must be added to the package inserts.

l. The "pregnancy-nursing warning" must be revised to come right before the [redacted] DRAFT LABELING [redacted]

m. For the back panels of bottle card, in the **READ THE LABEL** section, change the phrase that reads: "Keep the package insert. It contains important information" to read: DRAFT LABELING [redacted]

n. Identify the location of the expiration date and lot number on all immediate container and outer package labeling as required under 21 CFR 201.17.

2. Regarding the package insert and the pull-out label for 70 count bottles:

a. In the section heading "**How to use PEPCID AC Acid Controller Gelcaps**" under the statement "Use PEPCID AC® to treat or prevent these symptoms," change the word "treat" to [redacted] Also, include the approved name of the drug in the statements to read as follows: DRAFT LABELING [redacted]

b. For consistency with PEPCID AC (famotidine) Tablet labeling, under the instruction section, change "FOR RELIEF OF SYMPTOMS" to DRAFT LABELING [redacted] and "FOR PREVENTION OF SYMPTOMS" to [redacted] Under both subsections, replace the word "water" with the phrase [redacted]"

c. Under the subsection "TO PREVENT SYMPTOMS," change "1 hour" to "60 minutes."

d. Concerning the section titled "**Proven effective in clinical studies**":

i. To make the labeling more consumer friendly, we recommend revising the first statement above the graphs to "In clinical studies, Pepcid AC film-coated tablets were significantly better in relieving and preventing heartburn than placebo tablets (tablets without the medicine). Pepcid AC Gelcaps contain the same active ingredient." Delete the footnote that states "Data shown for tablets; gelcaps were shown to be bioequivalent."

ii. Delete the "% better" statements from the response rate graphs in the "**Proven effective in clinical studies**" section of the package inserts and in all labeling that contain these graphs.

e. To be consistent with the other acid reducer drug products, in the section titled "**Excess acid: a burning problem,**" replace the subsection phrase "**How to help avoid symptoms**" with DRAFT LABELING [redacted] with the following revised bullet statements:

DRAFT LABELING [redacted]

In addition, consider including these bulleted statements on the back panel of the carton labels.

3. Regarding the labeling for the individual blister units, remove "Gelcap" from the established name and replace it with [redacted] The dosage form name "Gelcaps" has not been officially recognized. In addition, use upper and lower case letters for consumer readability. Thus, the established name should read, "Famotidine Coated Tablet 10 mg."

4. Regarding the storage statement and expiry period:

   a. Revise the storage statement on all labeling for this drug product to "Store between 25°- 30°C (77°-86°F)." Data currently submitted to the NDA only supports storage in this temperature range.

   b. Be advised that the data submitted to date supports an expiry period of 24 months.

5. Be advised that the corner flag "NEW GELCAPS" as well as the phrase "Pepcid AC Acid Controller is Now Available in Gelcaps" on all labeling must be removed after the first 6 months of OTC marketing.

6. Be advised that further labeling revisions may be needed for any professional use samples of Pepcid AC (famotidine) Coated Tablets.

We also request that you consider reformatting the labeling as outlined in the February 27, 1997, Federal Register Notice "Over-the-Counter Human Drugs; Proposed Labeling Requirements" [62 FR 9024]. Note, however, that the proposed labeling requirements and the draft prototype label are subject to change pending finalization of this rule.

Finally, 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

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. In the absence of any such action FDA may proceed to withdraw the application. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

The drug product may not be legally marketed until you have been notified in writing that the application is approved.

If you have any questions, contact Michael Folkendt, Project Manager, at 301-443-0487.

Sincerely,

/S/ [redacted]

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

/S/ [redacted] 9-30-98

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

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