



DEPARTMENT OF HEALTH & HUMAN SERVICES

H7A-305

Food and Drug Administration
Rockville MD 20857

3 4 6 1 '00 APR 26 P 1 :30

Johnson & Johnson Merck
Attn: George Latyszzonek
Director, Regulatory Affairs
7050 Camp Hill Road
Fort Washington, Pennsylvania 19034-2299

APR 18 2000

Re: Docket No. 98N-0337
Comment No. APP7

Dear Mr. Latyszzonek:

Please refer to your April 10, 2000 submission of labeling to be used during the deferral period granted by the Agency in our March 23, 2000 correspondence for NDA 20-902, Pepcid AC Gelcaps (famotidine) 10 mg.

We have reviewed the labeling submitted and found it to be acceptable with the following corrections to be implemented within 180 days upon receipt of this letter, or the next printing, whichever comes first:

1. Under the **Directions** section, the words "**relieve**" and "**prevent**" and the phrase "**15 to 60 minutes before**" need to be bolded.
2. Under the **Other information** section, the degree symbols for the storage statement need to be added to read:
 - store between 25 - 30° C (77 - 86°F).

We also recommend that you consider adding:

1. The inactive ingredients and the toll free phone number 1-800-755-4008 for questions or comments.
2. The statement "Individual Pouch Not for Retail Sale" to be consistent with other sample pouches in your Pepcid AC product line.

If you have any questions, please contact Daniel Keravich, Regulatory Project Manager, or Elizabeth Yuan, Regulatory Project Manager, at 301-827-2222.

Sincerely yours,


Linda M. Katz, MD, MPH
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
Center for Drug Evaluation and Research

4/18/00

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