Folkendt
20-902

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 7/26/1999

FROM: Director,
Division of OTC Drug Products (HFD-560)

SUBJECT: Labeling Review
Pepcid AC Gelcaps

TO: Director,
Division of Gastrointestinal and Coagulation Drug Products (HFD-180)

Attached is our review of the labeling resubmission received on July 2, 1999.

Sincerely,

/S/ [redacted]

Charles J. Ganley, M.D.

APPEARS_THIS_WAY_ON_ORIGINAL

JUL 23 1999

Division of OTC Drug Products
Labeling Review

NDA No. 20-902	
TYPE OF SUBMISSION:	Revised labeling in response to approvable letter of 6/21/99
SPONSOR:	Merck Research Laboratories
DRUG PRODUCT:	Pepcid AC® Gelcaps
INDICATIONS:	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 foods and beverages
ACTIVE INGREDIENT:	Famotidine 10 mg per gelcap
SUBMISSION DATES:	July 2, 1999 and July 16, 1999 (facsimile)
REVIEWER:	Gloria Chang
REVIEW DATE:	July 8, 1999
PROJECT MANAGER:	Al Rothschild

Background: This submission (Attachment 1) contains revised labeling for Pepcid-AC Gelcaps and is in response to the Agency's approvable letter dated June 21, 1999 (Attachment 2). The submission includes labeling for the package insert, blister card, blister carton (6 and 30 count) and bottle carton and bottle labels (50, 54, and 70 count), and the dispensit for professional use sample pouches (30 count). At a June 24, 1999 teleconference (Attachment 3) between the sponsor and the Agency, the sponsor indicated that they were withdrawing the sample pouch label from the application at this time. In this submission, the sponsor noted in the summary of revisions section that the sample pouch is being deleted from this submission and will be resubmitted in the future with an accompanying request for an exemption from the standardized format requirements. In a teleconference between the Agency and the sponsor on July 15, 1999, we requested that the sponsor submit the graphic specifications for Pepcid AC Gelcap ***Drug Facts*** labeling. The sponsor submitted a facsimile on July 16, 1999 (Attachment 4) and noted that the original official submission of the response would be sent through the appropriate channels.

A. Agency's Requested Labeling Revisions and Reviewer's Comments

1. The blister carton label appears to be in a modified format. Revise this label to be consistent with the standardized format as described in § 201.66 (d)(10)(v). If space is needed to accommodate the new standardized format and language, the product attributes located at the top of the back panel should be minimized or deleted.

Reviewer's Comments. The sponsor has conformed to the standardized format except under the ***Directions*** section. The bulleted statement "do not use more than 2 gelcaps in 24 hours" needs to be moved and directly aligned under the prevention directions as the fourth bulleted statement. See prototype label.

2. The sample pouch label must be revised to include the horizontal barlines and hairlines and format as described in § 201.66(d)(10)(v).
Reviewer's Comments. The sponsor noted that the sample pouch is being withdrawn from this submission and will be resubmitted in the future with an accompanying request for an exemption from the standardized format requirements.

3. For the bottle carton, blister carton, and the dispensit, the bullets are gold (yellow) in color and do not appear to be 5-point type size. Thus, the bullets are not distinctive enough to provide a visual cue. To conform to § 201.66(d)(4), the bullets must be of 5-point type size, in a dark color, and be the same shape and color throughout the labeling such that these bullets are distinctive.
Reviewer's Comments. The sponsor noted that the bullets in the ***Drug Facts*** labels have been changed from the color gold to black and that the type size of the bullets are of 6-point type size. In a teleconference on July 15, 1999 between the Agency and the sponsor, we requested that the sponsor submit the graphic specifications for the Pepcid AC Gelcap labeling included in the July 2, 1999 submission. In response, on July 16, 1999, the sponsor submitted a facsimile (Attachment 4) of the official submission containing the requested specifications for the print, bullets, lines, etc., for the 6 and 30 count blister carton, 50, 54, and 70 count bottle carton, and the dispensit for the sample pouches. The graphic specifications stated in the facsimile are acceptable.

4. Revise the ***Warnings*** section as follows:

DRAFT_LABELING

d. Delete the proposed ***Warnings*** subsection DRAFT_LABELING ... ... This information is now incorporated in the "**Stop use and ask a doctor if**" subsection of the ***Warnings*** as the second bullet statement "you need to take this product for more than 14 days," and in the **Directions** section as a bullet