14 Pages Redacted
Draft Labeling

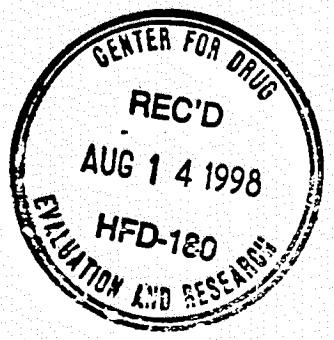
C80/Folkerdt

MEMORANDUM

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

DATE: 8/12/98 Rev. Date

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



SUBJECT: Labeling Review
Pepcid AC Acid Controller Gelcaps
(Famotidine 10 mg Tablets)
NDA 20-902

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

Attached is OTC's review of the draft labeling submitted by Merck Research Laboratories for the subject NDA.

/S/ [redacted]
Debra Bowen, M.D.

Division of OTC Drug Products
Labeling Review of NDA

NDA # 20-902
TYPE OF SUBMISSION: New Drug Application for New Dosage Form (Gelcaps)

SPONSOR: Merck Research Laboratories

DRUG PRODUCT: Pepcid AC Acid Controller Gelcaps
INDICATION: For Relief of heartburn, acid indigestion, and sour stomach
For Prevention of these symptoms brought on by consuming food and beverages

ACTIVE INGREDIENT: Famotidine 10 mg per Gelcap

SUBMISSION DATE: September 30, 1997
REVIEWER: Gloria Chang, R.Ph
REVIEW DATE: July 9, 1998
PM: Al Rothschild

Background: Pepcid AC Acid Controller (famotidine 10 mg) is a film-coated tablet that is currently marketed OTC for the treatment and prevention of heartburn (NDA 20-325, initial approval 4/25/95). In this submission, the sponsor requests approval of a gelatin coated, capsule-shaped tablet for the above approved indications. The sponsor claims efficacy is based on demonstration of bioequivalence to the already approved film-coated tablet. This submission contains xerox copies of the carton and package insert, the 70-count bottle card with corresponding pull-out bottle label and package insert, the pouches and the dispenser for the pouches, and the blisters. A diskette of the revised labeling was also received (See Attachment 1). The sponsor noted that the revised draft labeling is verbatim from the agency's previously approved labeling, dated 9/26/97, for PEPCID AC Acid Controller Film Coated Tablets, with the exception of text specific for the gelcap dosage form.

SPONSOR CHANGES/ REVIEWER'S COMMENTS

A. FRONT PANEL OF: CARTON, BOTTLE CARD, POUCHES, DISPENSERS FOR POUCHES, AND FRONT PAGE OF PACKAGE INSERTS

1. The sponsor added the corner flag text [redacted] on the Front Panel of the Carton and Bottle Card for 70-count bottles. The sponsor needs to be informed that the corner flag text [redacted] on the front panel of the carton and bottle card should be removed after the first 6 months of OTC marketing.

2. The sponsor deleted the phrases, "Now in Non-Prescription Strength" and "Can Be Used Up to Twice daily: Up to 2 Tablets in 24 hours," on the principal display panel of the labeling and replaced the phrases with DRAFT_LABELING [redacted] This revision is acceptable.

3. The sponsor added the word "Gelcaps" to the color bar line before the statement of identity for all labeling. The sponsor revised the statement of identity (SOI) to reflect the new dosage form by replacing "TABLETS" with "GELCAPS" to read: "ACID REDUCER/FAMOTIDINE GELCAPS 10 MG." The term "Gelcaps" has not been officially recognized and thus needs to be removed from the color bar before the statement of identity and from the statement of identity. The word "Gelcaps" in these places needs to be replaced with the word [redacted]

The sponsor can use "Gelcaps" on the front panel, but it must not be included in the statement of identity section. Further, if the word "Gelcaps" is used anywhere in the labeling, it must be defined. The term should appear in the declaration of net quantity of content statement followed by the definition of the dosage form in parenthesis (see comment A.5 below).

4. In accordance with § 201.61 (21 CFR 201.61), the established name of the drug should be followed by the pharmacologic category. The sponsor has used all upper case for the statement of identity. For consumer readability, the sponsor needs to use upper and lower case letters. Thus, the statement of identity in all the labeling should be revised to read: "Famotidine Tablets 10 mg/Acid Reducer."

5. The word "TABLETS" in the declaration of net quantity of contents text on the principal display panel of all the labeling was changed to "GELCAPS." This is acceptable provided that the sponsor defines the dosage form in parenthesis right after "Gelcaps." For consistency and consumer readibility, the sponsor should consider the use of upper and lower case letters in the net quantity of contents statement. Thus, the statement should read [redacted]

6. The sponsor has added a tablet (Gelcap) image on the front panel of carton packages. This revision is acceptable provided that the term "Gelcap" is defined as stated in comments A.3 and A.5 above.

7. In the upper (top) section of the front panel of the carton, pouch, dispenser, pull-out bottle label for the 70-count bottle, bottle card for the 70-count bottle, and pouch dispenser, the sponsor has included the phrase *"Relieves & Prevents Heartburn and Acid Indigestion."* The sponsor needs to remove the [redacted]

8. The sponsor should be advised that when the application (NDA # 20-801) requesting to change the trade name of the drug from "Pepcid AC Acid Controller" to [redacted] is approved, a labeling supplement for the subject product must be submitted to reflect the trade name change. For consistency and readability, the sponsor should use the same trade name for all labeling.

B. BACK PANEL OF: CARTON, POUCH, DISPENSER FOR POUCHES, BOTTLE CARD (70-count bottle), and PULL-OUT BOTTLE LABEL(70-count bottle)

1. The sponsor has included the Tamper Resistant/Tamper Evident statements for the following: