Division of OTC Drug Products
Labeling Review

NDA No. 20-902	
TYPE OF SUBMISSION:	Draft Labeling in response to FDA Approvable Letter of 9/30/98 and OTC Labeling Requirements Final Rule
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:	February 2, 1999 and May 17, 1999
REVIEWER:	Gloria Chang
REVIEW DATE:	May 20, 1999
PROJECT MANAGER:	Al Rothschild

Background: The February 2, 1999 submission (Attachment 1) for Pepcid AC Gelcaps is in response to the Agency's approvable letter dated September 30, 1998 (Attachment 2). Subsequently, the sponsor was informed that the labeling needed to comply with the OTC Labeling Requirements Final Rule (64 FR 13254) published March 17, 1999. On May 17, 1999, the sponsor submitted draft labeling to comply with the OTC Labeling Requirements Final Rule (Attachment 3). The submission includes color mock-ups for the bottle cartons and bottle labels (50, 54, and 70 count), blister carton and card (6 and 30 count), sample pouch dispensit, sample pouch, and package insert. In addition, the sponsor stated that other labeling changes were made for consistency with the approval letters dated September 24, 1998 (Attachment 4) for Pepcid AC Chewable Tablets (NDA 20-801) and for Pepcid AC and Mylanta AR Tablets (NDA 20-325/S007) dated November 9, 1998 (Attachment 5).

A. Reviewer's comments on labeling changes made in response to the September 30, 1998 approvable letter.

1. Concerning all labeling

a. The proprietary designation "Acid Controller" was removed from the proprietary name "Pepcid AC Acid Controller Gelcap" to read [redacted] This is acceptable.

b. The term "Gelcaps" was removed from the color bar before the statement of identity. The sponsor placed "Gelcaps" under the SOI. These changes are acceptable.

c. The statement of identity was revised to read "Famotidine Tablets 10 mg/Acid Reducer. Our requested labeling revision for the established name was "Famotidine Coated Tablets." The sponsor changed the established name to "Famotidine Tablets" stating that the change was consistent with FDA approved labeling for other marketed OTC products with a gelcap formulation. At this time, this revision is acceptable. The sponsor should be advised that the established name may be subject to change, pending the designation of an official name for the gelatin coated, capsule shaped tablet dosage form.

d. The declaration of net quantity of content statement was revised in accordance with our requested revision to read "Gelcaps (Gelatin Coated, Capsule Shaped Tablets). On the front panel of the 30 Gelcaps sample pouch dispenser carton (dispensit), the text "30 doses" was deleted. These changes are acceptable.

e. The underlining was deleted from the word "Prevents" in the text "Relieves & Prevents Heartburn and Acid Indigestion" on the principal display panel (PDP), and the words "relieves" and "prevents" in the first two bulleted statements on the top of the back panel. These changes are acceptable.

f. The Tamper Resistant/Tamper Evident statement on the pouches was moved from the **Warnings** section and placed on the front panel of the pouch. This is acceptable.

g. The word "broken" in the Tamper Resistant/Tamper Evident statements was replaced with the word "torn." This is acceptable.

h. In the second bulleted statement on the top of the back panel under the product attributes section, the word "consuming" was replaced with [redacted] This is acceptable.