

D. INDIVIDUAL BLISTER UNITS (Front Panel)

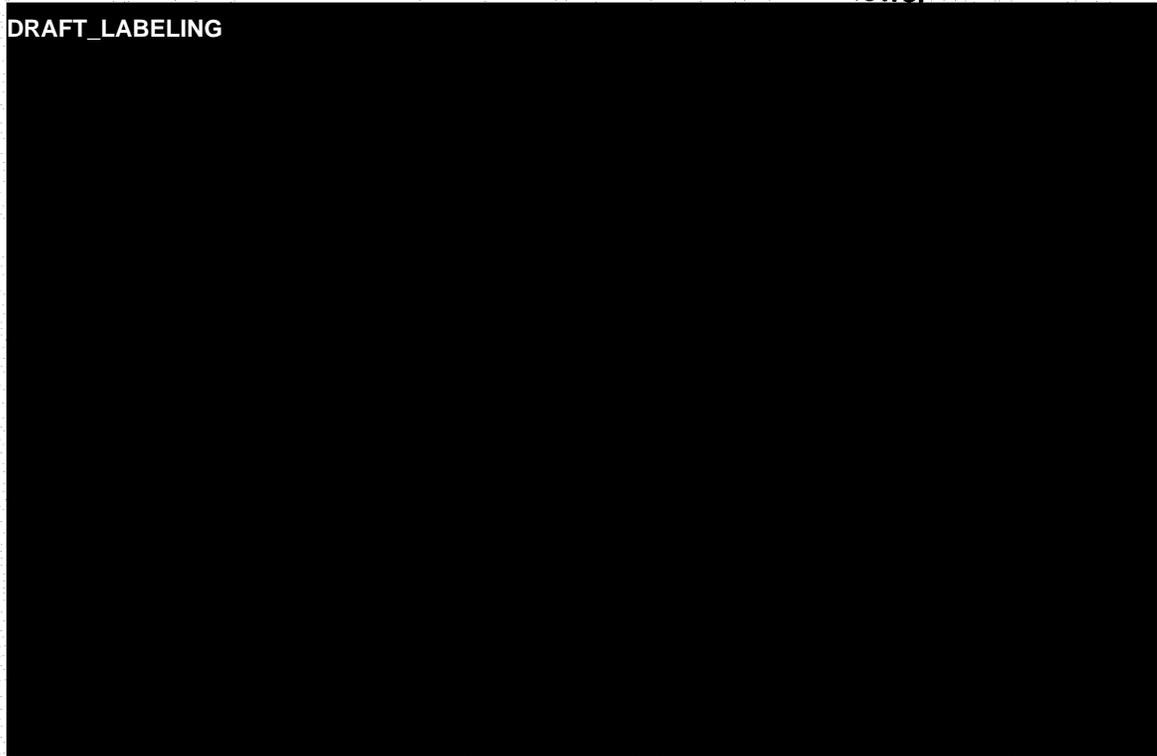
1. The sponsor needs to remove "Gelcap" from the established name and replace it with "tablet." Presently, the only officially recognized dosage form by both the Agency and the USP is famotidine tablets. The dosage form "Gelcaps" has not been officially recognized. We also suggest the use of upper and lower case letters for consumer readability. Thus, the established name should read,
... (See Agency Recommendations I.A.2. above.)

II. The following recommendations should be made at the next printing or within 180 days, whichever comes first.

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

1. To be consistent with the labeling of the other acid reducers, the Tamper Resistant/Tamper Evident statements in all of the labeling need to be revised to replace the word "BROKEN" with the word "torn." For consumer readability, the statement needs to be in upper and lower case letters. Thus, the Tamper Resistant/Tamper Evident statement should be revised as follows:

DRAFT_LABELING



2. At the top of the back panel of the carton, bottle card, and pouch dispenser, the sponsor should ... and from the second bullet, ... The phrase "(Read Consumer Leaflet before use)" in the first bullet should be changed to read: "(Read Package Insert before use)." because in the READ THE LABEL section, it is referred to as the "package insert." The sponsor should

consider including the title "Package Insert" on the front panel of the package insert labeling to make it easier for the consumer to identify the package insert.

3. To be consistent with the other acid reducers, the sponsor should consider the text in the proposed draft prototype label for Pepcid AC Acid Controller (Attachment 2) under the **Uses** section which replaces the word "consuming" with [REDACTED]. Thus, the bullets should read:

DRAFT_LABELING

4. The sponsor moved the **Active Ingredient** section before the **Uses** section. This is acceptable. The word "tablet" was replaced with "gelcap" in the **Active Ingredient** section and the word "tablets" was replaced with "gelcaps" in the **Directions** section. This is acceptable provided that the term "gelcap" is defined (see Agency Recommendations I.A.1 above). We suggest that the sponsor consider the labeling headings format and use of upper and lower case letters as proposed in the February 27, 1997 Proposed Labeling Requirements for OTC Drug Products (62 FR 9024) and the draft prototype label (Attachment 2).

5. Under the **Uses** section, the sponsor has underlined and/or bolded the phrases, "**For Relief**" and "**For Prevention**." To be consistent with other acid reducer drug products and with the February 27, 1997 Proposed Labeling Requirements for OTC Drug Products, under the **Uses** section, the bolding and underlining need to be removed. The **Uses** section should be revised to denote "heartburn" as the primary symptom, with other symptoms as secondary symptoms (see Attachment 2- draft prototype label) to read:

DRAFT_LABELING

6. The tablet image in the **Directions** section is acceptable at this time subject to the finalization of the proposed rulemaking on the Labeling Requirements for OTC Drug Products.

7. The third bullet under the **Directions** section that reads "Do not use with other acid reducers." should be moved to the **Warnings** section for consistency with other acid reducer drug products. (See Attachment 2.)

DRAFT_LABELING

9. The "pregnancy-nursing warning" needs to be revised to come right before the "Keep out of reach . . ." warning. (See Attachment 2.)

10. For the back panel of bottle card, the phrase in the **READ THE LABEL** section that reads: "Keep the package insert. It contains important information" should be changed to read: **DRAFT LABELING**

C. PACKAGE INSERT FOR THE: CARTON, 70-COUNT BOTTLES, AND DISPENSER FOR POUCHES

1. PACKAGE INSERT (Front Page)

(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," the word "treat" should be change to **DRAFT LABELING**. The approved name of the drug should be included in the statements to read as follows:

DRAFT LABELING

(b) For consistency with PEPCID AC Acid Controller tablets, under the instruction section, the sponsor should change "FOR RELIEF OF SYMPTOMS" to **DRAFT LABELING** "FOR PREVENTION OF SYMPTOMS" to **DRAFT LABELING**. Under both subsections, the word "water" should be replaced with the phrase **DRAFT LABELING**

(c) Under the subsection "TO PREVENT SYMPTOMS," "1 hour" should be changed to **DRAFT LABELING**

(d) In the section heading **DRAFT LABELING** to be consistent with the other acid reducer drug products, the sponsor needs to replace the subsection phrase "How to help avoid symptoms" with "Tips for Managing Heartburn" and the latest revised bullets as stated in Attachment 2. These tips should be included on the carton label; however, if space is at a premium, they may be included in the package insert.

III. The sponsor should be advised of the following:

1. The sponsor added the corner flag text "NEW GELCAPS" on the Front Panel of the Carton and Bottle Card for 70-count bottles. Under the Tamper Resistant/Tamper Evident statement on the top of the back panel of the 6 GELCAPS carton and the back panel of the pouch dispenser, the sponsor added the phrase "Pepcid AC Acid Controller is Now Available in Gelcaps." The sponsor needs to be informed that the corner flag text and the phrase should be removed after the first 6 months of OTC