

- A. On the top of the back panel of 6-dose carton, "DO NOT USE IF THE INDIVIDUAL BLISTER UNIT IS OPEN OR BROKEN."
- B. Under the Statement of Identity on the back panel of the Dispenser for the Pouches, "DO NOT USE IF POUCH IS OPENED."
- C. On the back panel of pouch, right after "Warnings:" reads "DO NOT USE IF POUCH IS OPEN OR BROKEN."
- D. On the top left corner of the Back Panel of the Bottle Card for the 70-count bottle, reads "DO NOT USE IF PRINTED FOIL INNER SEAL IS BROKEN."

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 [REDACTED]. 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:

- A. For the 6-dose carton, [REDACTED]
- B. For the Dispenser for Pouches, the word [REDACTED] needs to be added to read: [REDACTED]
- C. For the back panel of Individual Pouch, "Do not use if pouch is open or torn." The Tamper Resistant/Tamper Evident statement needs to be moved from the "Warnings" section. We suggest that the statement be placed right near the diagonal phrase: "While folded on line, tear open at the slit," or before the phrase "READ THE DIRECTIONS AND WARNINGS BEFORE USE."
- D. For the Back Panel of the Bottle Card (70-count bottle), the Tamper Resistant/Tamper Evident statement needs to be changed to be consistent with the agency's approvable letter of September 26, 1997 for Pepcid AC tablets (NDA 20-325/S006) to clarify the location of the foil inner seal and to add the word [REDACTED] to read: [REDACTED]

These changes can be made at the next printing or within 180 days whichever comes first.

2. 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 "Pepcid AC Acid Controller is Now Available in Gelcaps." The phrase "Pepcid AC Acid Controller is Now Available in Gelcaps." can only be used for 6 months after OTC marketing.

3. At the top of the back panel of the carton, bottle card, and pouch dispenser, the sponsor changed the first bullet from "1 tablet provides relief of heartburn and acid indigestion (Read Consumer Leaflet before use)" to "1 gelcap relieves heartburn and acid indigestion (Read Consumer Leaflet before use)." The second bullet reads: "PEPCID AC Acid Controller prevents heartburn and acid indigestion brought on by

consuming food and beverages." The sponsor should remove the underline from the word "..." respectively. The phrase "(Read Consumer Leaflet before use)" in the first bullet should be changed to read: "... because it is referred to as the "package insert" in the **READ THE LABEL** section. 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.

To be consistent with the other acid reducers, the sponsor should consider the text in the proposed new draft prototype label for Pepcid AC (Attachment 2) under the **Uses** section which replaces the word "consuming" with "eating and drinking." Thus, the bullets should read:

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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 comments A.3. and A.5.) 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 needs 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:

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These changes can be made at the next printing or within 180 days whichever comes first.

6. Under the **Directions** section, the sponsor added instructions for taking the gelcaps in the first and second bullet as follows:

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To be consistent with the Pepcid AC film-coated tablets, the phrase "For Relief of" and "For Prevention of" should be changed to DRAFT_LABELING

... To be consistent with other acid reducer drug products, in the prevention phrase under the **Directions** section, the "1 hour" needs to be changed to ...
... Under the "To relieve" and "To prevent" **Directions**, the phrase "a glass of" should be inserted between the words "with" and "water" to read: ...
... Under the **Directions** section, only the following words/phrase should be bolded: "relieve," "prevent," and "60 minutes before." (See Attachment 2.)

7. The sponsor added a third bullet under the **Directions** section to read:
... This text should be moved from the **Directions** to the **Warnings** section. (See Attachment 2.)

8. The sponsor added a tablet image in the **Directions** section. This is acceptable at this time. However, the acceptability of the tablet image graphic is subject to finalization of the agency's proposed rulemaking on Labeling Requirements for OTC Drug Products.

9. Under the **Warnings** section, the phrase, "(2 gelcaps)," was added after "Do not take the maximum daily dosage," and the word "tablets" was replaced with "gelcaps" in this section. This is acceptable at this time. However, the sponsor should consider the format and phrasing that is consistent with other acid reducer drug products and the proposed new OTC labeling format (see Attachment 2).

10. Under the **Warnings** section on the carton, pouch dispenser, pouch, bottle card and pull out bottle label, an allergy warning should be added. We recommend the following: **DRAFT LABELING**

...
... These changes can be made in 6 months or at the next printing, whichever comes first.

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

12. The sponsor changed the **READ THE LABEL** section on the carton label from "Keep the carton. It contains important information," to "Keep the carton and package insert. They contain important information." This change is acceptable. For the back panel of the bottle card, the phrase in the **READ THE LABEL** "Keep the package insert. It contains important information" should be changed to read: "Keep this back panel and package insert. They contain important information."

13. The sponsor included the storage instructions for the gelcaps. The approvability of the storage instructions will depend on the chemistry review.

14. The sponsor needs to identify the location of the expiration date and lot number for the carton, bottle card, bottle pull-out label and dispenser for pouch. In accordance with 21 CFR § 201.17, the expiration date shall appear on the immediate container and also the outer package.