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

I. PACKAGE INSERT (Front Page)

1. Reviewer's comments A.3, A.4, and A.8 above are also applicable.

2. In the section heading, "**A non-prescription stomach medicine**" the phrase, "It contains famotidine, a prescription-proven medicine," was deleted. Under the same section, "Tablets" was changed to "Gelcaps." This is acceptable. The tablet (Gelcap) image under the subsection "Product Benefits" is acceptable provided that "Gelcaps" is defined as stated in Comments A.3 and A.5 above.

3. 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 changed to [redacted] The term "Acid Controller" should be included in the statements to read [redacted] For consistency with PEPCID AC Acid Controller tablets, under the instruction section, the sponsor should change "FOR RELIEF OF SYMPTOMS" to [redacted] and "FOR PREVENTION OF SYMPTOMS" to [redacted] The sponsor should also consider the use of both upper and lower case letters in this section. Under both subsections, the word "water" should be replaced with the phrase [redacted] Under the subsection "TO PREVENT SYMPTOMS," "1 hour" should be changed to [redacted]

4. In the section heading "**Excess acid: a burning problem**," to be consistent with the other acid reducer drug products, the sponsor needs to replace the subsection phrase "**How to help avoid symptoms**" with [redacted] and the latest revised bullets as stated in Attachment 2. These "Tips" preferably should be included on the carton label; however, if space is at a premium, they may be included in the package insert.

5. Based on the submitted labeling, the Pouch Dispenser, Pouch, and Dispenser for Pouch package insert are for consumer use only, and not for professional use. Previous NDA submission, NDA 20-801 for Pepcid AC Acid Controller tablets contains labeling for professional use samples. If professional use only samples of Pepcid Acid Controller Gelcaps are intended to be distributed, the labeling may need revisions.

II. PACKAGE INSERT (Back Page)

1. In the section "**Proven effective in clinical studies,**" the first statement reads: "In clinical studies, PEPCID AC* was significantly better than placebo pills in relieving and preventing heartburn." The asterisk indicates the following footnote: "Data shown for tablets; gelcaps were shown to be bioequivalent." We recommend deleting the referenced footnote phrase and revising the first statement under the [redacted] section to read: "In clinical studies, PEPCID AC film-coated tablets were significantly better in relieving and preventing heartburn than placebo tablets (tablets without the medicine). PEPCID AC Acid Controller gelcaps show same results."

2. The [redacted] statements from the response rate graphs in the **"Proven effective in clinical studies"** section of the package inserts and in all labeling that contain these graphs need to be deleted.

D. INDIVIDUAL BLISTER UNITS

1. The sponsor needs to remove [redacted] 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, "Famotidine Tablet 10 mg." (See comment A.4 above.)

AGENCY RECOMMENDATIONS

I. The following recommendations need to be conveyed to the sponsor before this NDA can be approved.

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

1. The term "Gelcaps" added to the color bar before the statement of identity on the same line needs to be removed from all labeling. The sponsor must also remove the word "GELCAPS" from the statement of identity and replace it with the word "Tablets." The term "Gelcaps" has not been officially recognized. The sponsor can use "Gelcaps" on the front panel, but it must not be included in the statement of identity section. If the term "Gelcaps" appears on the front panel or anywhere else in the labeling, the sponsor must include the definition of the dosage form in parenthesis right after "Gelcaps" in the declaration of net quantity of content statement. Thus, the statement should read [redacted]

2. In the statement of identity section, 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 identify in all the labeling should be revised to read: [redacted]

3. 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 [redacted]

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

1. In the **Directions** section, the following changes should be made:

   (a) To be consistent with the Pepcid AC Acid Controller film coated tablets, the phrase "For Relief of" and "For Prevention of" should be changed to [redacted] and [redacted]

   (b) 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 [redacted]

   (c) Under the "To **relieve**" and "To **prevent**" **Directions**, the phrase "a glass of" should be inserted between the words "with" and "water" to read: [redacted]

   (d) Under the **Directions** section, only the following words/phrase should be bolded: "**relieve," "prevent," and "60 minutes before."** (See Attachment 2.)

   (e) The recommendations in (a) and (b) are also applicable to the Package Insert.

2. 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.

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

1. PACKAGE INSERT (Back Page)

   (a) We recommend deleting the referenced footnote phrase "Data shown for tablets; gelcaps were shown to be bioequivalent" and revising the first statement under the "**Proven effective in clinical studies**" section to [redacted]

   DRAFT_LABELING

   (b) The [redacted] statements from the response rate graphs in the "**Proven effective in clinical studies**" section of the package inserts and in all labeling that contain these graphs need to be deleted.