i. Under the **Uses** section, the underlining and bolding was deleted for the text "**For Relief**" and "**For Prevention**." The phrases were revised in accordance with the our requested changes to denote "heartburn" as the primary symptom, with other symptoms as secondary symptoms. These changes are acceptable.

j. An allergy alert warning was added as requested. However, the proprietary name needs to be deleted to read: "DRAFT_LABELING ...

k. The pregnancy-nursing warning was revised to come right before the "**Keep out of reach** . . .warning." This is acceptable.

l. Under the **Directions** section, the phrase "For Relief of" and "For Prevention " was revised to DRAFT_LABELING This is acceptable.

m. Under the **Directions** section, the following changes were made: (1) the word "water" was replaced with ... (2) the text "**1 hour**" was replaced with ... (3) only the following words/phrase were bolded "**relieve**," "**prevent**," and "**15 to 60 minutes before**," and (4) the third bulleted phrase "**Do not use with** other acid reducers" was moved to the **Warnings** section. These changes are acceptable.

n. The sponsor has removed the **READ THE LABEL** section, and has included the statement "● read the directions and warnings before use" under the **Other Information** section. This is acceptable; however, the sponsor should consider placing this statement outside the ***Drug Facts*** labeling section, in a conspicuous location such as the PDP or product attributes section.

o. Under the list of inactive ingredients, the ingredient "FD&C Red #10 was revised to read [redacted] ONDC needs to determine if this change is acceptable.

p. The location of the expiration date and lot number on the immediate container and outer package labeling was identified for the pouch dispenser, sample pouch, blister card, and 50, 54, and 70 tablets bottle carton panel. The sponsor needs to identify the location of expiration and lot number on the immediate bottle for the 50, 54, and 70 tablet bottles.

2. Regarding the package insert

a. The text "PACKAGE INSERT" was added to the top section of the package insert. This is acceptable.

b. In the section heading "**How to use PEPCID AC Gelcaps**" the word "treat" was changed to [redacted] Under the instructions subsection, the text "**FOR**

RELIEF OF" and "**FOR PREVENTION OF**" was changed to [redacted] The word "water" was replaced with the phrase [redacted] In the "**TO PREVENT SYMPTOMS**" subsection, "**1 hour**" was changed to [redacted] These changes are acceptable.

c. Under the subsection "**PEPCID AC** can be used up to twice daily (up 2 gelcaps in 24 hours)," for consistency with the directions, the phrase [redacted] DRAFT_LABELING [redacted]

d. In the section titled "**Excess acid: a burning problem**," the subsection heading "**How to help avoid symptoms**" and the bulleted statements under that section were replaced with DRAFT_LABELING [redacted] and revised bulleted statements. This change is acceptable.

e. In the section titled "**Proven effective in clinical studies**," the sponsor revised the first statement above the graphs in accordance with the Agency's request and deleted the footnote that states DRAFT_LABELING [redacted] DRAFT_LABELING [redacted] The [redacted] statements were also deleted from the response rate graphs. These changes are acceptable.

3. Regarding the labeling for individual blister units

a. The established name was revised to read "Famotidine Tablet