explanation of this section as it applies to the "Package Interchangeability Protocol" must be provided.

6. Regarding the drug product stability data:

   a. For the total "Degradates (% famotidine)" in the stability studies (see the amendment dated June 24, 1998, Attachment 3, Table 1) at 25°C/60%, 30°C/60%, and 40°C/75%, a scientific explanation must be provided for the fact that the material balance (assay plus Total Degradates) does not account for the decrease in the famotidine levels for periods of 12, 18, and 24 months.

   b. Verify that famotidine and/or famotidine degradates are not absorbed or adsorbed by the drug product [redacted] formation after the storage of drug product for long periods of time (i.e., 12, 18, and 24 months).

In addition, it will be necessary for you to submit draft labeling revised as follows:

1. Concerning all the labeling:

   a. Revise the proprietary designation for this drug product from "Pepcid AC® Acid Controller™ Gelcap" to [redacted]

   b. Regarding the terms "Gelcap" and "Gelcaps":

      i. Remove from all labeling the term "Gelcaps" added to the color bar before the statement of identity and place it with the rest of the proprietary designation "Pepcid AC®."

      ii. Replace the word "GELCAPS" in the statement of identity with the word [redacted]

      iii. Revise the declaration of net quantity of content statement to [redacted]

   c. As required under 21 CFR 201.61, the established name of the drug must be followed by the pharmacologic category in the Statement of Identity. Be advised that the Agency recognized dosage form name for this type of drug product is "Tablets." For consumer readability, use upper and lower case letters. Therefore, the statement of identity in all the labeling should be revised to read: "Famotidine Tablets 10 mg/Acid Reducer."

   d. Remove the underlining from the word "Prevents" in the phrase *"Relieves & Prevents*

*Heartburn and Acid Indigestion"* on the front panel of all labeling. Similarly, remove the underlining from the words "relieves" and "prevents" from the first bullet statement, [redacted] and from the second bullet statement, [redacted]

e. Concerning the Tamper Resistant/Tamper Evident statements:

i. The Tamper Resistant/Tamper Evident statement on the pouches must be moved from the "**Warnings**" section. We suggest that the statement be placed near the diagonal phrase: "While folded on line, tear open at the slit," or before the phrase "READ THE DIRECTIONS AND WARNINGS BEFORE USE."

ii. Replace the word "BROKEN" with the word "torn." In addition, the word "torn" must be added to this statement on the pouch dispenser and bottle labels. 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:

[redacted]

f. For consistency with terminology used in the **READ THE LABEL** section, replace the words "Consumer Leaflet" with the words "Package Insert" in the phrase "(Read Consumer Leaflet before use)" in the first bullet statement at the top of the back panel of the labels. In addition, please 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.

g. 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 in the declaration of net quantity of content statement. Please consider use of the labeling headings format and the use of upper and lower case letters as proposed in the February 27, 1997 Proposed Labeling Requirements for OTC Drug Products (62 FR 9024).

h. To be consistent with the other acid reducers, replace the word "consuming" with "eating and drinking." Thus, the bullets should read:

DRAFT LABELING [redacted]

i. Under the **Uses** section, the phrases, "**For Relief**" and "**For Prevention**." are underlined and/or bolded. 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, remove the bolding and underlining in these phrases. Also, revise the **Uses** section to denote "heartburn" as the primary symptom, with other symptoms as secondary symptoms to read:

- 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 and drinking certain food and beverages.

j. Revise the **Directions** section on all labeling as follows:

i. For consistency, revise the phrase "For Relief of" and "For Prevention of " to [redacted]
DRAFT LABELING [redacted]

ii. To be consistent with other acid reducer drug products, change "**1 hour**" to [redacted] throughout the labeling.

iii. Under the "To **relieve**" and "To **prevent**" **Directions** add the phrase "a glass of" between the words "with" and "water" to read: [redacted]

iv. Under the **Directions** section, bold only the following words/phrase: **"relieve," "prevent,"** and **"60 minutes before."**

v. 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.

vi. Move the third bullet under the **Directions** section that reads "Do not use with other acid reducers." to the **Warnings** section for consistency with other acid reducer drug products.

k. Under the **Warnings** section on the labeling for the cartons, bottles, pouch dispensers,