requirements final rule (64 FR 13254). (See prototype draft label - Attachment 6.)

1. For the bottle carton, blister carton, and the dispensit, the sponsor used a gold (yellow) color contrast for the box barline, horizontal barlines and hairlines, and for the bullets used in the text of the label. In accordance with § 201.66(d)(4), the bullets do not appear to be at least of a 5-point type size. Thus, the bullets are not distinctive enough to provide a visual cue. The sponsor needs to make the bullets ~~at least~~ a 5-point type size and in a dark color in the same shape and color throughout the labeling that would make them distinctive.

2. Under the **Warnings section**, the sponsor needs to add or revise the following statements:

I. Revise the Allergy alert warning to read:

DRAFT_LABELING

ii. Under the heading **"Do not use"** to read:

DRAFT_LABELING

iii. Under the heading **"Stop use and ask a doctor if"** to read

DRAFT_LABELING

iv. The heading and statements under the heading that reads [redacted]

DRAFT_LABELING [redacted] needs to be deleted. This information needs to be incorporated under the heading **"Stop use and ask a doctor if** you need to take this product for more than 14 days" and in the **Directions** section as "do not use more than 2 tablets in 24 hours." (See prototype draft label -Attachment 6.)

3. Under the **Directions section,** the sponsor needs to revise the format and language as follows: (See Prototype Draft Label - Attachment 6.)

DRAFT_LABELING [redacted]

4. The blister carton label appears to be in a modified format and needs to be changed to the standardized format. For the blister carton labeling, the standardized OTC labeling format based on the OTC labeling requirements final rule is appropriate. If space is needed to accommodate the standardized format and language, the product attributes located at the top of the panel can be minimized or deleted.

5. For the sample pouch label, the sponsor needs to include the horizontal barlines and hairlines and format in accordance with § 201.66(d)(10)(v).

6. 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] needs to be added.

7. The sponsor needs to identify the location of expiration and lot numbers for the immediate bottle container for the 50, 54, and 70 tablet bottles.

8. The sponsor changed the established name to "Famotidine Tablets" stating that the change was consistent with FDA approved labeling for other marketed OTC products with a gelcap formulation. At this time, this change is acceptable. The sponsor should be advised that the established name may be subject to change, pending the designation of an official name for the gelatin coated, capsule shaped tablet dosage form.

9. On the PDP, the corner flagged text "NEW! GELCAPS" was revised to read "NEW!" on the 6 and 30 gelcap blister packs. The sponsor should use the original text "New! GELCAPS" because the word "NEW!" alone is misleading and may imply that this is a new product, rather than a new dosage form.
On the PDP of the bottle cartons, the sponsor added the phrase "NEW! Convenient Bottle." The sponsor needs to clarify the "NEW!" statement as to whether the package size is new or what makes the bottle more convenient than