statement "do not use more than 2 tablets in 24 hours."
Reviewer's comments. The sponsor has revised these warnings on the ***Drug Facts*** labels and they are acceptable. See A.1 above for comments on the blister carton label.

5. Revise the format and text of the ***Directions*** section to:

DRAFT_LABELING

Reviewer's Comments. As noted above under A.1, with the exception of the blister carton label, the ***Drug Facts*** labeling for the bottle cartons and the dispensit for professional use sample pouches (30 count) reflect the requested revisions. We note that for the immediate bottle labels (50, 54, and 70 count), only the text was revised. See Reviewer's comments in A.15 below.

6. Regarding the package insert, modification of the headings and format should be made to be consistent with the labeling format from the OTC labeling final rule.

DRAFT_LABELING

Reviewer's Comments. The phrase "Use PEPCID AC to relieve or prevent these symptoms:..." was revised to read

DRAFT_LABELING

This is acceptable. The sponsor noted that at this time, they are not reformatting the package insert to be consistent with the OTC labeling final rule stating that package inserts are not subject to the format requirements. See Reviewer's Other Comments below under B.1.

7. Identify the location where the expiration date and the lot number are printed for the 50, 54, and 70 tablet bottles.
Reviewer's Comments. The location for the expiration date and lot number are identified. This is acceptable.

8. The text in the corner flag on the principal display panel of the blister card cartons "NEW!" is misleading because it can imply that this is a new product, rather than a new dosage form of an existing product. Revise the text in this flag to "NEW! GELCAPS." In addition, please commit to deleting this flag after six months of marketing.
Reviewer's Comments. The sponsor revised the text and committed to deleting the revised flag after six months of marketing. This revision is acceptable.

9. Concerning the yellow flag on the principal display panel of the bottle cartons, clarify the text in this flag as to whether the package size is new or what makes the bottle more convenient than other bottles. In addition, please commit to deleting this flag after six months of marketing.

Reviewer's Comments. The sponsor clarified that the yellow flag on the principal display panel will be revised to "New Easy-Open Bottle" in order to qualify the previous use of the word "New." This revision is acceptable. The sponsor needs to commit to deleting the revised flag after six months of marketing.

10. At the top of the back panel of the carton label for the bottles, blister cards, and the dispensit cartons, the word "Fast" in the statement "PEPCID AC is Now Available in a Fast and Easy-to-Swallow Gelcap" is misleading and must be deleted. In addition, please commit to deleting this revised statement after six months of marketing.

Reviewer's Comments. The sponsor deleted the word "Fast" from the statement and committed to deleting the flag after six months of marketing. This revision is acceptable.

11. Revise the storage statement under the "*Other information*" section from [redacted] DRAFT_LABELING

Reviewer's Comments. The sponsor should consider adding a space before and after the "-" between the Centigrade and the Fahrenheit temperatures for consumer readability.

12. For consistency with the indication under the *Uses* section, we request that you revise the following:

a. All instances of the phrase "Relieves & Prevents Heartburn and Acid Indigestion" to [redacted]

b. At the top of the back panel of the cartons and sample pouch dispensit, revise the bulleted phrases:

i. "1 gelcap relieves heartburn and acid indigestion" to DRAFT_LABELING [redacted] DRAFT_LABELING

ii. "PEPCID AC prevents heartburn and acid indigestion..." to [redacted] DRAFT_LABELING

Reviewer's Comments. The labels reflect these revisions and are acceptable.

13. To better conform to § 201.61 stating that the statement of identity must in direct conjunction with the most prominent display of the proprietary name and must be in bold face type on the principal display panel in a size related to the most prominent printed matter, we request that the type size of the statement of identity be increased to a size related to the type size of the proprietary name "Pepcid AC."

Reviewer's Comments. Although the sponsor stated that the statement of identity has been increased, we would prefer that it be in a size more related to the proprietary name.

14. We request that you consider repeating the statement "read the directions and warnings before use" outside the *Drug Facts* labeling section in a conspicuous location.

Reviewer's Comments. The sponsor stated that due to lack of available space, they are not repeating the statement "read the directions and warnings before use." This is acceptable.

15. For the immediate bottle label, the sponsor should consider following the provisions in

§ 201.66(d)(10)(i) through (d)(10)(v) for the modified format. For consumer readability, we strongly suggest using a 6-point type size.

Reviewer's Comments. The sponsor stated that they are not choosing to format the immediate bottle label according to the OTC labeling final rule because the immediate bottle label is not subject to the final rule if the bottle container is in an outer carton that does conform to the standardized format of the final rule. We recommend that, for consumer readability, that the type-point size of the immediate bottle label be increased to at least a 6-point type size.

B. Reviewer's Other Comments on Labeling

1. Regarding the package insert, for safety reasons, under the section "How to use PEPCID AC Gelcaps" the sponsor should include the age range,... DRAFT_LABELING

2. If additional information relating to the safety or effectiveness of this drug becomes available, revision of the labeling may be required.

AGENCY RECOMMENDATIONS

I. The following modification needs to be made in order for this NDA to be approved.

A. Regarding the blister carton label. Under the ***Directions*** section , the bulleted statement "do not use more than 2 gelcaps in 24 hours" needs to be moved and directly aligned under the prevention directions as the fourth bulleted statement. As labeled, the statement is misleading and implies that the limit of 2 gelcaps in 24 hours only applies for the prevention directions. See prototype label.

II. The following labeling changes need to be made within 180 days or at the next printing, whichever comes first.

A. The sponsor clarified that the yellow flag on the principal display panel will be revised to "New Easy-Open Bottle" in order to qualify the previous use of the word "New." This revision is acceptable. However, the sponsor needs to commit to deleting the revised flag after six months of marketing.