

10 mg.” This is acceptable at this time. See Reviewer’s comment at A.1.c above.

4. Regarding the storage statement and expiry period

a. The revised storage statement is in accordance with our requested change. However, to be consistent with the language used in examples of product labeling in the OTC labeling requirements final rule, the storage statement that reads “store between 25 - 30°C (77 - 86°F)” should be revised to read...

...

B. Reviewer’s comments on May 17, 1999 submission

1. Principal Display Panel

a. For consistency with the indication under the **Uses** section, the sponsor should consider changing the text to “Relieves & Prevents Heartburn due to Acid Indigestion.” On the bottle carton, 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 this bottle more convenient than others.

- b. The sponsor stated that the proprietary name text "Pepcid AC" is taller, and noted that this was consistent with the trademark/graphic design approved for PEPCID AC Chewable tablets in the approval letter dated September 24, 1998. Under 21 CFR 201.61, the SOI needs to be 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. The sponsor should consider increasing the type size of the SOI in a size related to the size of the proprietary name "Pepcid AC."
- c. The single horizontal red bar under the proprietary name was replaced with three shorter, narrower bars graphics and the SOI moved to under the three bars. This is acceptable.
- d. The text "Just 1 gelcap per dose" was moved to the side of the label and revised to **DRAFT LABELING** This is acceptable.
- e. 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. The sponsor should be advised that the corner flag text on all labeling must be removed after the first 6 months of marketing.

2. Drug Facts Labeling

a. The labeling is not in conformance with § 201.66 of the OTC labeling requirements final rule. (See prototype draft label - Attachment 6.) The following revisions need to be made.

(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 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:

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