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 **"When using this product** do not take the maximum daily dosage (2 gelcaps) for more than 2 weeks continuously except under the advice and supervision of a doctor" 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

DRAFT_LABELING

(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) Under the product attributes section on the bottle, blister, and dispensit cartons, the word ... in the statement DRAFT_LABELING DRAFT_LABELING is misleading and needs to be deleted. Sponsor also needs to be made aware that the revised statement must be removed after the first 6 months of marketing.

(6) For the immediate bottle label, we suggest that the sponsor follow the provisions in § 201.66(d)(10)(i) through (d)(10(v) for the modified format. For consumer readability, we suggest using a 6-point type size.

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

3. Other labeling comments

a. For the package insert, under the section heading "**A non-prescription stomach medicine,** " the third bulleted text DRAFT_LABELING ... was added. The statement is unclear and misleading. Because the sponsor already has a similar statement under the heading DRAFT_LABELING the third bulleted text should be deleted.

b. For the back panel of the cartons and sample pouch dispensit, under product attributes section, for consistency with the indication in the **Uses** section of the ***Drug Facts*** label, the bulleted phrases "1 gelcap relieves heartburn and acid indigestion" should be revised to read DRAFT_LABELING ... The bulleted phrase "PEPCID AC prevents heartburn and acid indigestion. . .." should be revised to read DRAFT_LABELING ...

AGENCY RECOMMENDATIONS

I. The following modifications need to be made in order for this NDA to be approved.

A. The labeling is not in conformance with § 201.66 of the new OTC labeling