CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

NDA 20-958 / S-002

LABELING REVIEW(S)

Division of OTC Drug Products Labeling Review

NDA 20-958/SCF-002
Drug Product: Pepcid Complete (Berry Flavored)
Dosage form: chewable tablet
Active Ingredients per tablet: **Famotidine 10 mg**
Calcium hydroxide 800 mg
Magnesium hydroxide 165 mg

Indication: **relieves heartburn associated with acid indigestion and sour stomach**
Sponsor: **Merck Research Laboratories**

Date of Submission : **July 5, 2001**
Reviewer: **Gloria Chang, IDS/Pharmacist, HFD-560**
Date of Label Review: **September 21, 2001**
Project Manager: **Daniel Keravich**

Background:
This review evaluates the electronically submitted labeling, also submitted as colored hardcopy labeling (Attachment 1) for the following: 5-and 35-count carton label, and 25-count carton professional dispensit, 50-count immediate bottle label, trade pouch (1-count), sample pouch (1-count), and package insert. The submission is a supplement to NDA 20-958 to add a new berry flavored product and provides changes in the labeling and chemistry section of Pepcid ™Complete. NDA 20-958 (mint flavored) was approved 10/16/2000.

I. Reviewer's General Labeling Comments (Applicable to all labeling)

1. Principal Display Panel (PDP)

a. Although the sponsor indicated the Statement of Identity (SOI) was enlarged (see 10/12/2000 commitment letter for NDA 20-958), it does not appear to be prominently displayed in direct conjunction with the proprietary name in accordance with 21 CFR 201.61. We suggest that the SOI (i.e., "Acid Reducer + Antacid") be more prominently displayed.

b. The sponsor needs to be reminded that the "***NEW! BERRY*** FLAVORED" statement must be removed after 180 days of marketing.

2. Package Insert

a. The package insert labeling is acceptable.

3. Tamper Evident Statements - Carton Labels, Bottle Label, Trade and Sample Pouch

a. The Tamper Evident statements are acceptable.

II. Reviewer's Specific Labeling Comments

1. Carton Labeling: Carton label (5-count and 35-count) and Professional Dispensit (25 count)

a. The Drug Facts labeling format and content (21 CFR 201.66) are acceptable.

2. Immediate 50-count Bottle Label
   a. Under the ***Other information*** section of the Drug Facts labeling, revise the bulleted statements to be vertically aligned in accordance with 21 CFR 201.66(d)(4).

3. Sample Pouch and Trade Pouch label
   a. The modified Drug Facts labeling format is in accordance with 21 CFR 201.66 (d)(10)(i) through (v).

Reviewer's Recommendations.
The following revisions are needed.

1. In the ***Other information*** section of the bottle labeling for all container sizes, revise the bulleted statements to be vertically aligned in accordance with 21 CFR 201.66(d)(4).
2. On the PDP of all the labeling, we suggest that the SOI (i.e., "Acid Reducer +Antacid") be more prominently displayed in direct conjunction with the proprietary name in accordance with 201.61.
3. The sponsor needs to be reminded that the "***NEW! BERRY*** FLAVORED" statement must be removed after 180 days of marketing.
4. The approval of labeling is subject to the approval of the chemistry changes submitted in this supplement.

The above comments can be conveyed to the sponsor.

Gloria Chang 9/28/01
Gloria Chang, R.Ph.
Interdisciplinary Scientist, HFD-560

10/2/01
Helen Cothran, B.S.
Team Leader, HFD-560

Attachment

NDA 20-958/SCF002
HFD-180:Levine/Kacuba
HFD-560:Ganley/Katz/Cothran/Segal/G.Chang/Robinson/Keravich/T4Binder with Labels/Prescott

Drafted: ChangG:9/21/01
Edited: Cothran: 9/27/01/9/28/01
F/T: ChangG:9/28/01
HFD-560:Division File
Doc ID:NDA20958-SCFBerryrev.doc

10 page(s) of draft labeling has been removed from this portion of the review.

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Gloria Chang
10/1/01 03:14:27 PM
INTERDISCIPLINARY

Helen Cothran
10/3/01 02:46:17 PM
INTERDISCIPLINARY