CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-327

OTHER REVIEW(S)

Office of Nonprescription Products
Center for Drug Evaluation and Research
Food and Drug Administration

Amended Labeling Supplement Review

SUBMISSION DATE: April 22, 2009 and 24	**PDUFA DATE:** May 16, 2009
NDA	22-327/000/BL
Drug Product	Prevacid 24 HR
Sponsor	Donna Coughlin Associate Director North America Region Liason, Digestive Health Global Regulatory Affairs Novartis Consumer Health, Inc. 200 Kimball Drive Parsippany, NJ 07054-0622
Active Ingredient	Lansoprazole delayed-release capsules, 15 mg
Labeling submitted	42-ct outer carton 28-ct carton 14-ct bottle 14-ct carton 14-ct carton hang tag Club Pack Package insert
Reviewer	Mary S. Robinson
Review Date	5-4-2009

Background

This submission is submitted by Novartis Consumer Health (NCH), Inc. for Lansoprazole delayed-release capsules, 15 mg for the treatment of frequent heartburn (occurs 2 or more days a week). This submission contains revised labeling recommended in the agency's March 30 and April 21, 2009 conveyed to the sponsor via e-mail. On April 20, 2009, FDA representatives discussed it's March 30, 2009 labeling comments with the sponsor. This submission contains draft printed labeling for the PREVACID 24HR proposed retail packages (28-ct carton, 14-ct bottle, 14-ct carton, 42-ct Club Pack, 14 count hang tag) and the corresponding package insert.

This submission updates the Prevacid 24HR labeling. No other changes are proposed to the retail packages and bottle label. This is a review of the labeling contained in this submission.

Reviewer's comments

The reviewer's comments and recommendations refer to the 14-count inner bottle, 14-, 28-, and 42-count cartons, the 14-count hang tag, the club pack and the corresponding package insert.

4 Page(s) Withheld

✓ Trade Secret / Confidential (b4)

_____ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Other Review(s) - 1

b(4)

Reviewer's Recommendations

The proposed labeling in the submissions of April 22 and 24, 2009 is acceptable and this labeling can be approved.

The sponsor should be requested to submit final printed labeling that is identical to the draft labeling in the April 22 and 24, 2009 submissions.

Mary S. Robinson, M.S.
Regulatory Review Chemist

Concurrence
Debbie Lumpkins
Team Leader

7 Page(s) Withheld

_____ Trade Secret / Confidential (b4)

✓ Draft Labeling (b4)

_____ Draft Labeling (b5)

_____ Deliberative Process (b5)

Withheld Track Number: Other Review(s) - 2

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

/s/

Mary Robinson
5/5/2009 01:00:08 PM
INTERDISCIPLINARY

Debbie Lumpkins
5/5/2009 01:01:36 PM
INTERDISCIPLINARY

LABELING FILING CHECKLIST FOR A NEW NDA/BLA

Drug Name: Prevacid 24 HR (Lansoprazole 15 mg delayed-release capsule)	**Applicant:** Novartis Consumer Health	**Letter Date:** July 15, 2008
NDA Number: 22327	**NDA Type:** New	**Stamp Date:**

On **initial** overview of the NDA application for RTF:

	Content Parameter	Yes	No	Comments
1	Is Index sufficient to locate necessary labeling?	✓		
2	Has labeling for all SKUs been submitted (e.g., blister card, pouch, immediate container, carton label and package insert labeling, etc)?	✓		
3	Does the submission contain the annotated specifications for the "Drug Facts" label?	✓		
4	Is a new trade name being proposed? If multiple trade names, is the RLD trade name identified?	✓		

Any Additional Comments:

Mary S. Robinson, MS — August 22, 2008
Reviewing Regulatory Review Chemist — Date

Debbie L. Lumpkins
Team Leader — Date

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

/s/

Mary Robinson
9/2/2008 05:54:51 PM
INTERDISCIPLINARY

Debbie Lumpkins
9/4/2008 11:18:08 AM
INTERDISCIPLINARY