DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-327 **NDA APPROVAL**

Novartis Consumer Health, Inc.
Attention: Kim Stranick, Ph.D.
Vice President & Head, Global Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054

Dear Dr. Stranick:

Please refer to your new drug application (NDA) dated July 15, 2008, received July 16, 2008, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act, for Prevacid 24 HR (15mg lansoprazole) capsules.

We acknowledge receipt of your submissions dated November 7 and 13, and December 12, 2008 and January 9, 16 and 19, February 20, March 4, 6, 11, and 20, April 6, 22, 24 and 27, 2009.

This new drug application provides for the nonprescription use of Prevacid 24 HR (15 mg lansoprazole) capsules for the treatment of frequent heartburn (occurs 2 or more days per week).

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revision listed below.

(b) (4)

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the enclosed labeling, except with the revisions listed above and noted on the enclosed labeling, (consumer information leaflet, 14-count bottle label and 14-count carton label submitted April 22, 2009, 14-count carton with hangtag, 28- and 42-count carton labels submitted April 24, 2009, and the 42-count "Club" SKU

carton label submitted April 22, 2009), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

The final printed labeling should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 22-327**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product with FPL that is not identical to the approved labeling text and in the required format may render the product misbranded and an unapproved new drug.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for this application.

(b) (4)

Please submit one market package of the drug product when it is available.

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mary Vienna, Regulatory Project Manager, at (301) 786-4150.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, M.D.
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joel Schiffenbauer

5/18/2009 04:08:40 PM