DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022327/S-004 **SUPPLEMENT APPROVAL**

Novartis Consumer Health, Inc.
Attention: Marissa M. Fletcher, Ph.D.
North American Region Liaison, Digestive Health
Global Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054

Dear Dr. Fletcher:

Please refer to your March 17, 2010 supplemental new drug application, received March 17, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevacid® 24HR (lansoprazole) delayed-release capsules, 15mg.

We acknowledge receipt of your submissions dated April 26 and September 1, 2010.

This "Prior Approval" supplemental new drug application provides for the addition of a 14-count physician sample packaging configuration with associated labeling, the addition of a "Walmart" version of the approved 42-count carton, and minor editorial label changes for the 14-count immediate container (bottle), the 14-, 28- and 42-count cartons and the 42-count "Club" carton labels.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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 (the 14-count immediate container (bottle) label submitted April 26, 2010; the 14-, 28-, 42-count and 42-count "Walmart" carton and 42-count "Club" carton front panel submitted March 17, 2010; the 14-count carton with hangtag submitted April 26, 2010; and the 14-count physician sample carton, 42-count "Club" carton back panel, the consumer information leaflet and the 14-count physician sample package insert submitted September 1, 2010), 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 022327/S-004**." Approval of this submission by FDA is not required before the labeling is used.

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
5600 Fishers Lane, Room 12B05
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) 796-4150.

Sincerely,

{See appended electronic signature page}

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

Enclosure
Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22327	SUPPL-4	NOVARTIS CONSUMER HEALTH INC	Prevacid OTC (lansoprazole) 15mg

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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
09/15/2010