



NDA 022327/S-013

**SUPPLEMENT APPROVAL**

Novartis Consumer Health, Inc.  
Attention: Marie C. Vicinanza, M.S., R.D.  
Associate Director, Global Regulatory Affairs  
200 Kimball Drive  
Parsippany, NJ 07054

Dear Ms. Vicinanza:

Please refer to your July 28, 2010 supplemental new drug application, received July 28, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevacid® 24HR (lansoprazole) delayed-release capsules, 15mg.

This “Prior Approval” supplemental application proposes to change the text color used for the consumer information leaflet to black text on a white background.

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

**LABELING**

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 consumer information leaflets submitted November 3, 2010), and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 14-ct immediate container (bottle), the 14-, 28- and 42-count cartons, the 14-count physician sample carton, the 14-count hangtag carton, the 42-count “Club Carton” or the 42-count “Walmart” carton, we request that you submit this as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

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 (June 2008).” 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-013.**” Approval of this submission by FDA is not required before the labeling is used.

## **DRUG REGISTRATION AND LISTING**

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

## **REPORTING REQUIREMENTS**

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

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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.**  
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/s/  
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JOEL SCHIFFENBAUER  
04/19/2011