DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022327/S-020

SUPPLEMENT APPROVAL

Novartis Consumer Health, Inc.
Attention: Marie Vicinanzo
Associate Director, Regulatory Affairs
200 Kimball Drive
Parsippany, NJ 07054-0622

Dear Ms. Vicinanzo:

Please refer to your Supplemental New Drug Application (sNDA) dated March 27, 2012, received March 27, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prevacid® 24HR (lansoprazole) delayed-release capsules, 15 mg.

We acknowledge receipt of your amendments dated August 9 and August 24, 2012.

This "Changes Being Effected" supplemental new drug application proposes the following change to the ***Warnings*** section of the "Drug Facts" label:

> Following the subheading "**Stop use and ask a doctor if**," add a bullet that reads
> - you get diarrhea

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 revisions listed below:

1. In Drug Facts under ***Warnings***, "**Stop use and ask a doctor if**", move the statement "[bullet] You get diarrhea" from the first-bulleted statement to the fourth-bulleted statement. As a reminder, Novartis agreed in the August 9, 2012 amendment to S-020 to implement this minor editorial change at the next printing or no later than January 17, 2013.

2. For the 2-count professional and consumer sample tip cards, the backer panel of the 42-count "Club Pack" carton, and the Consumer Information Leaflets (for the carton and Club Pack configurations), in the consumer information section "**Warnings and When to Ask Your Doctor**," move the statement "[bullet] You get diarrhea" from the first-bulleted statement to the fourth-bulleted statement in the "**Stop use and ask a doctor if**" subheading.

3. For the 2-count consumer sample tip card, in Drug Facts under ***Warnings***, remove the hairline inserted between the "***Warnings***" title and the "**Allergy alert:**" subheading.

4. For the 2-count professional sample tip card, add a bullet before "Do not use for more than 14 days unless directed by your doctor." in the "**How to Take PREVACID®24HR**" section located in the first column of the consumer tip information.

LABELING

Submit final printed labeling, with the revisions listed above, 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 2-count consumer sample tip card label submitted August 24, 2012, the 2-count professional sample tip card and the 14-count carton labels submitted August 9, 2012, and the 2-count immediate container (blister) label, the 14-count immediate container (bottle) label, the 28-, 42-, 42-"Walmart", 42-"Daytona", 42-"Bonus" and 42-count "Club Pack" carton labels and Consumer Information Leaflets (carton and Club Pack) submitted March 27, 2012, 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 (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-020**." 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 questions, call Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURE(S):
Carton and Immediate Container Labeling

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
09/19/2012