DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021229/S-024

**SUPPLEMENT APPROVAL**

Procter & Gamble Company
Attention: Vicki Ireland, Pharm.D.
Senior Scientist, Regulatory Affairs
(Agent for AstraZeneca LP)
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Ireland:

Please refer to your Supplemental New Drug Application (sNDA) dated March 14, 2012, received March 14, 2012, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC® (omeprazole magnesium) delayed-release tablets, 20 mg.

We acknowledge receipt of your amendments dated March 30 and June 7, 2012.

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

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 following minor editorial revision to the submitted 14-count sample carton and the 14-count sample carton with coupon at the time of next printing:

- In the **Drug Facts** title, remove the space between the letters "r" and "u" in the word "**Dr ug**" so that the title reads as:

  "**Drug Facts**"

## LABELING

Submit the following final printed labeling (FPL), with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed.

Submit final printed labeling identical (except for the minor editorial changes to the packaging configurations as denoted above) to the 14-count original carton label submitted on March 14, 2012 and to the following labels submitted on March 30, 2012:

- 2-count original and wildberry flavor sample carton labels
- 14-count original and wildberry inner carton labels
- 28-count original and wildberry flavor carton labels
- 42-count original and wildberry carton labels
- 42-count "Club Pack" carton label

Submit final printed labeling identical (except for the minor editorial changes to the packaging configurations as denoted above) to the following labels submitted on June 7, 2012:

- 14-count wildberry flavor carton label
- 14-count sample carton and sample with coupon carton labels
- 14-count Olympic rings logo carton label
- 28-count Olympic rings logo carton label
- 42-count Olympic rings logo carton label
- 42-count "Club Pack" Olympic rings logo carton label

Your submission dated and received June 7, 2012, notified FDA that one label is representative. Therefore, any changes approved for the wildberry flavor 14-count carton label will be incorporated into the wildberry flavor 14-count carton with hangtag label. Please note that representative labeling is not acceptable for FPL submissions.

Even though no revisions were made to the 2-count immediate container (pouch) and the14-count immediate container (blister card) as part of this supplement, you should submit the 2-count immediate container (pouch) and the 14-count immediate container (blister card) 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 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 021229/S-024**." 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}*

Andrea Leonard-Segal, M.D., M.S.
Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton Labels

---

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

---

/s/

---

ANDREA LEONARD SEGAL
09/13/2012