DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021229/S-023

SUPPLEMENT APPROVAL

The Proctor & Gamble Company
Proctor & Gamble Mason Business Center
Attention: Vicki Ireland
Senior Scientist, Regulatory Affairs
Agent for AstraZeneca LP
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. Ireland:

Please refer to your Supplemental New Drug Application (sNDA) dated March 1, 2011, received March 2, 2011, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC® (omeprazole magnesium) delayed-release tablets, 20mg.

We acknowledge receipt of your amendment dated July 27, 2011.

This "Prior Approval" supplemental new drug application provides for the addition of the Olympic rings logo on the principal display panel to indicate that Prilosec OTC is an official sponsor of the Olympics. This change would apply to the 14-, 28-, and 42- count carton labels and the 42-count "Club Pack" carton label for the original Prilosec OTC tablet only.

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.

In Drug Facts under *Warnings*, **Ask a doctor or pharmacist before use if you are** taking, delete the comma after the word "clopidogrel" in the first bullet so that it reads as follows:
"[bullet] warfarin, clopidogrel or cilostazol (blood-thinning medicines)".

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 enclosed labeling (the 14-, 28-, and 42- count outer (retail) carton labels and the 42-count "Club Pack" carton label submitted on July 27, 2011), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 14-count immediate container (blister card) and the 14-count inner carton labeling, 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 021229/S-023**." 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}

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

ENCLOSURE(S):
Carton and 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/

ANDREA LEONARD SEGAL
08/29/2011