DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021229/S-019

SUPPLEMENT APPROVAL

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

Dear Ms. Linton:

Please refer to your September 3, 2010 supplemental new drug application, received September 3, 2010, 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 submission dated January 18, 2011.

This supplemental application, submitted as a "Changes Being Effected" supplement, proposes the following change: the revision of the current bulleted statement, "taking warfarin or clopidogrel (blood-thinning medicine)," under the Drug Facts Warnings subheading, "Ask a doctor or pharmacist before use if you are taking" to read:

"**Ask a doctor or pharmacist before use if you are** taking:
- warfarin, clopidogrel or cilostazol (blood-thinning medicine)"

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.

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 2-count sample tip card, 14-count inner carton label, 14-, 28- and 42-count outer (retail) carton labels and 42-count "Club Pack" carton label submitted on January 18, 2011), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 2-count immediate container (pouch) and 14-count immediate container (blister card), 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-019**." 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.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to 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, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

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

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
02/25/2011