DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021229/S-014

SUPPLEMENT APPROVAL

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

Dear Ms. Galletta:

Please refer to your Supplemental New Drug Application (sNDA) dated January 29, 2010, received January 29, 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 amendment dated April 8, 2010.

This "Prior Approval" supplemental new drug application proposes changing the opening instructions on the immediate container (blister card) from "Push tablet through foil" to "Push tablet through printed side"; changing the instruction "Do not crush tablets in food" to "Swallow whole"; and adding "One 14-day course of treatment" and "Do not take for more than 14 days or more often than every 4 months unless directed by the doctor" to the center cell of the immediate container (blister card).

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.

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 (14-count immediate container (blister card) submitted January 29, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 14-, 28-, 42-count, and (club pack) 42-count cartons, we request that you submit these cartons 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 (October 2005)*". 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-014**." Approval of this submission by FDA is not required before the labeling is used.

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 CDERMedWatchSafetyAlerts@fda.hhs.gov, and to the following address:

MedWatch
Food and Drug Administration
Suite 12B-05
5600 Fishers Lane
Rockville, MD 20857

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 Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE:
Immediate Container Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21229	SUPPL-14	ASTRAZENECA LP	PRILOSEC (OMEPRAZOLE MAGNESIUM)

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
07/06/2010