DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-229/S-013

The Proctor & Gamble Company
Proctor & Gamble Mason Business Center
Attention: Linda C. Jones
Principal Scientist, Regulatory Affairs
Agent for AstraZeneca LP
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Ms. Jones:

Please refer to your supplemental new drug application dated March 17, 2009, received March 18, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec OTC® (20 mg omeprazole magnesium) delayed-release tablets.

We acknowledge receipt of your submissions dated July 9 and August 31, 2009.

This supplemental new drug application proposes the addition of information from the current Prilosec OTC package insert to the outer carton, removal of the package insert, and revision of Drug Facts to include the drug-drug interaction with antiretroviral drugs to treat HIV infection, for the sample-tip card, the 14-ct inner carton, the 14-, 28- and 42-count outer (retail) carton label and 42-count "Club" SKU tall and horizontal carton labels.

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 and with the minor editorial revisions listed below:

1. Delete the periods after the statements in "Tips for Managing Heartburn" that appears on the side or back panel for the 14-, 28- and 42-counts, and the inside of the sample tip card. This is consistent with other acid reducers.

2. On the sample-tip card, the 42-count vertical club carton, and the 42-count horizontal club carton, under the heading "Directions", bullet 4, add a period at the end of the second sentence as follows: "[bullet] children under 18 years of age: ask a doctor. Heartburn in children may sometimes be caused by a serious condition."

3. On the sample tip card, the inner and outer 14-count cartons, 28-count, 42-count vertical, and 42-count horizontal cartons under the heading "Directions", subheading "14-Day Course of Treatment", last bullet, add a period at the end of the second statement as follows: "[bullet] swallow whole. Do not chew or crush tablets."

The final printed labeling (FPL) must include the revisions listed and be otherwise identical to the enclosed labeling (sample-tip card, 14-count inner carton label, 14-, 28- and 42-count outer (retail) carton label and 42-count "Club" SKU tall and horizontal carton label submitted on August 31, 2009) and must be formatted in accordance with the requirements of 21 CFR 201.66. These revisions are terms of the approval of this application.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-229/S-013**." Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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 Nonprescription Products
Center for Drug Evaluation and Research

Enclosure

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21229	SUPPL-13	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
09/09/2009