DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-229/S-008

Proctor & Gamble Health Care Research Center
Attention: Barbara A. Kochanowski, Ph.D.
Director, Global Product Safety and Regulatory Affairs
Agent for AstraZeneca LP
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Kochanowski:

Please refer to your supplemental new drug application dated July 17, 2007, received July 18, 2007, 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 January 11, 15, and 16, 2008.

This supplemental new drug application proposes to change the design of the Prilosec OTC logo throughout the labeling, reformat the 2-count professional sample card, redesign the inner panels of the 2-count consumer sample card, reformat the package insert, and redesign the principal display panel (PDP) of the 14-count child-resistant and non-child-resistant inner cartons, and the14-count, 28-count non-child-resistant, and 42-count outer cartons. This supplemental application does not propose changes to the Drug Facts or blister card backing.

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 revision listed below.

Per your January 16, 2008 commitment, remove the word [redacted] from the statement "NEW LOOK! SAME [redacted] RELIEF!" on all PDPs prior to implementation of the revised labeling.

The final printed labeling (FPL) must be identical to, and include the revision listed above, the enclosed labeling (2-count professional sample card submitted January 11, 2008; 2-count consumer sample card, 1-count sample card inner pouch, package insert, 14-count and 14-count non-child-resistant inner cartons, and the 14-count, 28-count non-child-resistant, and 42-count outer cartons submitted July 17, 2007), and must be formatted in accordance with the requirements of 21 CFR 201.66. The revision is a term 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-008**." Approval of this submission by FDA is not required before the labeling is used.

We remind you to remove the statement “NEW LOOK! SAME RELIEF!” from the label 6 months after the revised label is implemented.

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 20852

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, contact Geri Smith, Regulatory Project Manager, at geri.smith@fda.hhs.gov or (301) 796-2204.

Sincerely,

{See appended electronic signature page}

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

Enclosure

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

/s/

Andrea Segal

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