



NDA 21-229/S-010

The Proctor & Gamble Company
Proctor & Gamble Mason Business 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 December 20, 2007, received December 21, 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 31, May 23, and June 13, 2008.

This “Changes Being Effected in 30 days” supplemental new drug application proposes the replacement of the 7-count, child-resistant, peel-and-push-through style blister cards with the 7-count, child-resistant, push-through style blister cards, approved under supplemental NDA 21-229/S-005 for a 28-count package size, for the 14-, 28- and 42-count Prilosec OTC package sizes, incorporating the flag “NOW EASIER TO OPEN BLISTER CARD”.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (7-count blister card, 14-count inner carton label, 14-, 20- and 42-count outer (retail) carton label and 42-count “Club” SKU carton label) and must be formatted in accordance with the requirements of 21 CFR 201.66, where applicable.

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-010.**” Approval of this submission by FDA is not required before the labeling is used.

Per your June 11, 2008 commitment, we remind you that the “NEW LOOK! SAME RELIEF” “NOW EASIER TO OPEN BLISTER CARD” flag must be removed from the label and labeling, wherever it

appears, by November 2008 (6 months after introduction of the revised label into the OTC marketplace).

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}

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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