



NDA 21-229/S-009

The Proctor & Gamble Company
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 November 2, 2007, received November 5, 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 submission dated February 12, 2008.

This supplemental application proposes the replacement of the two 7-count, child-resistant, peel-and-push-through style blister cards with a single 14-count, child-resistant, push-through style blister card for the 14-, 28-, and 42-count carton Prilosec OTC package sizes, and associated labeling changes to the blister cards to reflect this packaging change.

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.

The final printed labeling (FPL) must be identical to the enclosed labeling (14-count blister card, 14-count inner carton label, 14-, 28-, and 42-count outer carton labels, and 42-count "Club" carton label submitted February 12, 2008), 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-009.**" Approval of this submission by FDA is not required before the labeling is used.

We remind you of your agreement in your submission dated November 2, 2007. This agreement is listed below.

1. Test the stability of the first product lot of push-through style blister card packaging in accordance with the AstraZeneca LP standard post-approval drug product stability protocol.

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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