



NDA 21-229/S-005

The Procter & Gamble Company
Attention: Barbara A. Kochanowski, Ph.D.
Director, Global Product Safety and Regulatory Affairs
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Kochanowski:

Please refer to your supplemental new drug application dated April 6, 2006, received April 7, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec OTC (20mg omeprazole magnesium) delayed-release tablets.

This supplemental new drug application provides for the addition of a non-child resistant 28-count package to the current packaging configurations available for the product.

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 (28-count package carton, 14-count inner carton, and blister card labeling submitted April 6, 2006), and must be formatted in accordance with the requirements of 21 CFR 201.66.

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-005.**" 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 20852

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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 LCDR Keith Olin, Regulatory Project Manager, at (301) 796-0962.

Sincerely,

{See appended electronic signature page}

Susan Johnson, Ph.D.
Associate Director
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/

Susan Johnson
10/2/2006 03:16:32 PM