DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-229/S-006

Procter & Gamble Health Care Research Center
Attention: Barbara A. Kochanowski, Ph.D.
Director, Global Product Safety and Regulatory Affairs
8700 Mason-Montgomery Rd
Mason, OH 45040-9462

Dear Dr. Kochanowski:

Please refer to your supplemental new drug application dated September 15, 2006 received September 19, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec OTC (20 mg omeprazole magnesium) tablets.

We acknowledge receipt of your submission dated March 16, 2007.

This supplemental new drug application provided for additional drug interaction warnings to Drug Facts and to the package insert for the retail and sample packages.

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-, 28- and 42- count carton label with Drug Facts, 14-count inner carton label with Drug Facts (for use in 28- and 42 count package sizes), 2-count professional sample inner and outer panel label, 2-count consumer sample inner and outer panel label, and the package insert), 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-006**." 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

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

Sincerely,

{See appended electronic signature page}

Andrea Leonard-Segal, MD
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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