DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-229/S-002

Proctor & Gamble
Attn: 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 July 20, 2004, received July, 22, 2004 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec OTC (20mg omeprazole) Tablets.

This "Changes Being Effected" supplemental new drug application provides revised labeling for the 2-count sample size.

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 attached labeling, submitted July 20, 2004, and must be formatted in accordance with the requirements of 21 CFR 201.66.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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) 827-2293.

Sincerely,

{See appended electronic signature page}

Curtis Rosebraugh, M.D., M.P.H.
Deputy Director
Division of Over-the-Counter Drug Products
Office of Drug Evaluation V
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/

Curtis Rosebraugh

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