DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021229/S-025

SUPPLEMENT APPROVAL

Procter & Gamble Company
Attention: Vicki Schofield, Pharm.D.
Regulatory Affairs Manager
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Schofield:

Please refer to your Supplemental New Drug Application (sNDA) dated March 14, 2013, received March 14, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC® (omeprazole magnesium) delayed-release tablets, 20.6 mg.

We acknowledge receipt of your amendments dated April 12 and June 11, 2013.

This "Prior Approval" supplemental new drug application proposes to add a flag with the statement "14 BONUS tablets" to the principal display panel (PDP) of the 42-count original flavor container, and a slash through the number "28" with the number "42" written above as the declaration of net quantity of contents.

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

LABELING

Submit final printed labeling as soon as they are available, but no more than 30 days after they are printed. The final printed labeling (FPL) must be identical to the 42-count original carton label submitted on April 12, 2013, and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Though no revisions were made to the 14-count immediate container (blister) or 14-count inner carton labels as part of this supplement, you should submit the 14-count immediate container (blister) and 14-count inner carton labels as part of the FPL for this supplement in order to maintain a record of the complete labeling (count sizes and packaging configurations) being approved as part of this supplement.

The final printed labeling should be submitted electronically according to the guidance for industry titled "Providing Regulatory Submissions in Electronic Format – Human

Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (June 2008)." Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 021229/S-025**." Approval of this submission by FDA is not required before the labeling is used.

DRUG REGISTRATION AND LISTING

All drug establishment registration and drug listing information is to be submitted to FDA electronically, via the FDA automated system for processing structured product labeling (SPL) files (eLIST). At the time that you submit your final printed labeling (FPL), the content of labeling (Drug Facts) should be submitted in SPL format as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf. In addition, representative container or carton labeling, whichever includes Drug Facts, (where differences exist only in the quantity of contents statement) should be submitted as a JPG file.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have questions, contact Jeff Buchanan, Regulatory Project Manager, at (301) 796-1007.

Sincerely,

{See appended electronic signature page}

Joel Schiffenbauer, MD
Deputy Director
Division of Nonprescription Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):
Carton Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOEL SCHIFFENBAUER
09/06/2013