



NDA 021229/S-017

**SUPPLEMENT APPROVAL**

The Proctor & Gamble Company  
Proctor & Gamble Mason Business Center  
Attention: Lisa Linton  
Senior Scientist, Regulatory Affairs  
Agent for AstraZeneca LP  
8700 Mason-Montgomery Road  
Mason, OH 45040-9462

Dear Ms. Linton:

Please refer to your Supplemental New Drug Application (sNDA) dated June 23, 2010, received June 24, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC<sup>®</sup> (omeprazole magnesium) delayed-release tablets, 20mg.

We acknowledge receipt of your amendment dated November 23, 2010.

This "Changes Being Effected" supplemental new drug application provides for the revision of the current bulleted statement, "warfarin (blood-thinning medicine)," under the Drug Facts Warnings subheading, "Ask a doctor or pharmacist before use if you are taking" to read:

- "Ask a doctor or pharmacist before use if you are taking**
- warfarin or clopidogrel (blood-thinning medicine)"

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 enclosed labeling (the 2-count sample tip card, 14-count inner carton label, 14-, 28- and 42-count outer (retail) carton labels and 42-count "Club Pack" carton label submitted on November 23, 2010), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 2-count immediate container (pouch) and 14-count immediate container (blister card), we request that you submit this 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 (October 2005)*. 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-017.**” 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.

## **LETTERS TO HEALTH CARE PROFESSIONALS**

If you issue a letter communicating important safety related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch  
Food and Drug Administration  
5600 Fishers Lane, Room 12B05  
Rockville, MD 20857

## **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 any questions, call Mary Vienna, Regulatory Project Manager, at (301) 796-4150.

Sincerely,

*{See appended electronic signature page}*

Joel Schiffenbauer, M.D.  
Deputy Director  
Division of Nonprescription Evaluation  
Office of Drug Evaluation IV  
Center for Drug Evaluation and Research

Enclosure  
Labeling

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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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JOEL SCHIFFENBAUER  
12/20/2010