



NDA 021229/S-020

SUPPLEMENT APPROVAL

The Proctor & Gamble Company
Proctor & Gamble Mason Business Center
Attention: Lisa R. Linton, Pharm.D.
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 December 17, 2010, received December 20, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC[®] (omeprazole magnesium) delayed-release tablets, 20mg.

We acknowledge receipt of your amendments dated May 10 and June 6, 2011.

This "Prior Approval" supplemental new drug application provides for the addition of a 14-count sample carton, with and without a coupon.

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 and with the minor editorial revisions listed below.

In Drug Facts under *Warnings*, **Ask a doctor or pharmacist before use if you are** taking, add an "s" to "medicine" in the first bullet so that it reads as follows:
"[bullet] warfarin, clopidogrel, or cilostazol (blood-thinning medicines)."

In the coupon sentence "LIMIT OF ^(b)₍₄₎ LIKE COUPONS in same shopping trip", change the ^(b)₍₄₎ to "1".

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 14-count sample carton label with coupon, 14-count sample carton label without coupon, and coupon submitted on May 10, 2011), and must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Even though no revisions were made to the 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 (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-020.**” 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 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 Clinical Evaluation
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURE(S):

Carton and Container 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
06/20/2011