



NDA 21229/S-026

SUPPLEMENT APPROVAL

The Proctor and Gamble Company
Attention: Vicki Schofield, PharmD
Regulatory Affairs Manager
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. Schofield:

Please refer to your Supplemental New Drug Application (sNDA) dated October 1, 2013, received October 1, 2014, 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 November 6 and 18, 2013, and December 23, 2014. The December 23, 2014 submission constituted a complete response to our June 13, 2014, action letter.

This "Prior Approval" sNDA proposes revised artwork for all marketed labels for both the base and wildberry flavors of Prilosec OTC. The complete response, dated December 23, 2014, includes the following additional label warnings requested in the October 31, 2014 CBE-0 supplement request letter:

Under the Drug Facts Warnings heading "**Ask a doctor or pharmacist before use if you are taking**", adding the new bulleted statement:

- methotrexate (arthritis medicine)

and by revising the existing immunosuppressant drug interaction warning by adding mycophenolate mofetil:

- tacrolimus or mycophenolate mofetil (immune system medicines).

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 (FPL) for Prilosec OTC (omeprazole magnesium) delayed-release tablets, as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the following labels submitted on December 23, 2014 and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

- 2-count immediate container (sachet), original & wildberry flavor
- 14-count immediate container (blister card), original & wildberry flavor
- 2-count sample tip card, original & wildberry flavor
- 14-count inner carton, original & wildberry flavor
- 14-count carton, original & wildberry flavor
- 14-count sample carton, original flavor
- 28-count carton, original & wildberry flavor
- 42-count carton, original & wildberry flavor
- 42-count “Bonus” carton, original flavor
- 42-count “Club Pack” carton, original flavor

The FPL 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 21229/S-026.**” Approval of this submission by FDA is not required before the labeling is used.

MARKET PACKAGE

Please submit one market package of the drug product when it is available.

If sending via USPS, please send to:

Mr. Jeffrey Buchanan
Food and Drug Administration
Center for Drug Evaluation and
Research
White Oak Building 22, Room: 5461
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

If sending via any carrier other than USPS
(e.g., UPS, DHL), please send to:

Mr. Jeffrey Buchanan
Food and Drug Administration
Center for Drug Evaluation and
Research
White Oak Building 22, Room: 5461
10903 New Hampshire Avenue
Silver Spring, Maryland 20903

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 CAPT Janice Adams-King, Safety Regulatory Project Manager, at (301) 796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, M.D.
Acting Deputy Director for Safety
Division of Nonprescription Drug Products
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/

VALERIE S PRATT
06/22/2015