



NDA 021229/S-032

SUPPLEMENT APPROVAL

The Proctor and Gamble Company
Attention: Vicki Schofield, PharmD
Regulatory Affairs Manager
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Schofield:

Please refer to your Supplemental New Drug Application (sNDA) dated and received December 20, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC (omeprazole) delayed-release tablets, 20 mg.

This “Prior Approval” sNDA provides for the addition of “24HR” and the statement “May take 1 to 4 days for full effect” to the principal display panel (PDP) of all outer cartons, except for the 2-count sample carton; removal of the description of frequent heartburn “occurring more than 2 days a week” from the PDP; and addition of a 2D barcode to all inner and outer cartons.

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.

If you intend to market other package configurations in the future (e.g., cartons containing greater than 14 tablets, package sizes greater than 42-count), we will expect submission of a prior approval supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use. We encourage you to contact us about the content and format of such a supplement prior to submission.

LABELING

Submit final printed labeling (FPL), as soon as they are available, but no more than 30 days after they are printed. The FPL must be identical to the labels listed on page 2, and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Original formulation:

- 2-count sample carton (sachet) [February 16, 2018]
- 2-count tip card [February 16, 2018]
- 14-count immediate container (blister) [December 20, 2017]
- 14-count inner carton [April 20, 2018]
- 14-count outer carton [April 20, 2018]
- 28-count outer carton [April 20, 2018]
- 42-count outer carton [April 20, 2018]
- 42-count outer carton with ‘3 PACK’ flag [April 20, 2018]
- 42-count outer carton with ‘14 BONUS Tablets’ flag (club pack) [April 20, 2018]

Wildberry flavor:

- 14-count immediate container (blister) [December 20, 2017]
- 14-count inner carton [April 20, 2018]
- 14-count outer carton [April 20, 2018]
- 42-count outer carton [April 20, 2018]

The FPL should be submitted electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 021229/S-032.**” 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 Alina Salvatore, Regulatory Project Manager, at (240) 402-0379.

Sincerely,

{See appended electronic signature page}

Karen Murry Mahoney, MD, FACE
Deputy Director
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/

KAREN M MAHONEY
06/12/2018