



NDA 21229/S-033

SUPPLEMENT APPROVAL

The Proctor and Gamble Company
(Authorized Agent for AstraZeneca Pharmaceuticals LP)
Attention: Maria Petrey, MS, RAC
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 October 9, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC (omeprazole magnesium) delayed-release tablet, 20 mg.

This “changes being effected” supplemental new drug application provides for “**Ask a doctor or pharmacist before use if you are** taking a prescription drug. Acid reducers may interact with certain prescription drugs.” This update to the drug-drug interaction warning is in response to the Agency’s communications of June 29 and August 10, 2018.

We have completed our review of this application. 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 must be identical to the labeling listed below and must be in the “Drug Facts” format (21 CFR 201.66), where applicable.

Labels submitted on February 15, 2019:

Original (base):

- 2-count sample carton (sachet) with “See current Drug Facts” flag
- 2-count sample carton (sachet) without “See current Drug Facts” flag

Labels submitted on October 9, 2018 and the Drug Facts font and format specifications submitted on January 14, 2019:

Original (base):

- 14-count inner carton
- 14-count outer carton with “See current Drug Facts” flag
- 14-count outer carton without “See current Drug Facts” flag

- 28-count outer carton with “See current Drug Facts” flag
- 28-count outer carton without “See current Drug Facts” flag
- 42-count outer carton with “See current Drug Facts” flag
- 42-count outer carton without “See current Drug Facts” flag
- 42-count outer carton with ‘3 PACK’ and “See current Drug Facts” flags
- 42-count outer carton with ‘3 PACK’ flag
- 42-count outer carton (club pack) with ‘14 BONUS Tablets’ and “See current Drug Facts” flags
- 42-count outer carton (club pack) with ‘14 BONUS Tablets’ flag

Wildberry flavor:

- 14-count inner carton
- 14-count outer carton with “See current Drug Facts” flag
- 14-count outer carton without “See current Drug Facts” flag
- 42-count outer carton with “See current Drug Facts” flag
- 42-count outer carton without “See current Drug Facts” flag

The final printed labeling 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 (April 2017, Revision 4)*. For administrative purposes, designate this submission “**Final Printed Labeling for approved NDA 21229/S-033.**” Approval of this submission by FDA is not required before the labeling is used.

If you are interested in marketing other package configurations in the future, (e.g., bottles containing greater than 14 tablets, package sizes greater than 42-count), a prior approval labeling supplement that includes data to adequately demonstrate appropriate consumer comprehension of limitations of use must be submitted.

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 Health Project Manager, at 301-796-3713.

Sincerely,

{See appended electronic signature page}

Valerie Pratt, MD
Deputy Director for Safety
Division of Nonprescription Drug Products
Office of Drug Evaluation IV
Center for Drug Evaluation and Research

ENCLOSURES:
Carton and Container Labeling

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

VALERIE S PRATT
04/04/2019 04:27:42 PM