DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 021229/S-031

SUPPLEMENT APPROVAL

AstraZeneca LP (Agent-Procter & Gamble Co.)
Attention: Vicki Schofield, PharmD
Regulatory Affairs Manager
Mason Business Center
8700 Mason-Montgomery Road
Mason, OH 45040-9462

Dear Dr. Schofield:

Please refer to your supplemental New Drug Application (sNDA) dated and received October 6, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec OTC (omeprazole) delayed release tablet, 20 mg.

This "Changes Being Effected" (CBE-0) supplemental new drug application provides for a labeling revision to the ***Warnings*** section of the Drug Facts Labeling to add the following text under the **Stop use and ask a doctor if: "**you develop a rash or joint pain" (after the bullet that reads "you get diarrhea").

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. Include in your submission final printed labeling for the items listed in the table below. The final printed labeling must be in the "Drug Facts" format (21 CFR 201.66), where applicable.

Submit final printed labeling identical to the following labels submitted on October 6, 2017:

Original:

- 2-count sample carton (sachet)
- 14-count immediate container (blister)
- 14-count inner carton
- 14-count outer carton
- 28-count outer carton
- 42-count outer carton

- 42-count outer carton with '3 PACK' flag
- 42-count outer carton with '14 BONUS Tablets' flag (club pack)

Wildberry flavor:

- 14-count immediate container (blister)
- 14-count inner carton
- 14-count outer carton
- 42-count outer carton

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 (May 2015, Revision 3).* For administrative purposes, designate this submission "**Final Printed Labeling for approved NDA 21229/S-031**." Approval of this submission by FDA is not required before the labeling is used.

We remind you that, if you should be interested in marketing other package configurations in the future (e.g., individual containers containing greater than 14 tablets, total package sizes greater than 42-count), we expect submission of a prior approval supplement that includes data to demonstrate consumer comprehension of limitations of use. You are encouraged to contact the Division of Nonprescription Drug Products, prior to submission of such a supplement, about the content and format of the supplement.

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 CDR Daniel Reed, Regulatory Project Manager, at (301) 796-2220.

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

ENCLOSURE:
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
04/03/2018