DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19810/S-099
NDA 22056/S-015

SUPPLEMENT APPROVAL

AstraZeneca LP
Attention: Judy W Firor
Director, Regulatory Affairs
1800 Concord Pike PO Box 8355
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your Supplemental New Drug Applications (sNDA) dated and received November 8, 2013, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Prilosec (omeprazole) Delayed-Release Capsules and Prilosec (omeprazole magnesium) Delayed-Release Oral Suspension.

We acknowledge receipt of your amendments dated January 27, 2014, February 4, 2014 and February 17, 2014.

We also refer to our letter dated October 10, 2013, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for Prilosec. This information pertains to the risk of fetal harm in pregnancy, with the use of esomeprazole, the S-isomer of omeprazole.

These supplemental new drug applications provides for revisions to the labeling for Prilosec. The agreed upon changes to the language included in our October 10, 2013, letter are noted in the attached label. The following sections were impacted by the labeling revisions in the package insert:

HIGHLIGHTS OF PRESCRIBING INFORMATION
- USE IN SPECIFIC POPULATIONS

FULL PRESCRIBING INFORMATION: CONTENTS
FULL PRESCRIBING INFORMATION
8. USE IN SPECIFIC POPULATION
   8.1 Pregnancy
   8.4 Pediatric use
13 NONCLINICAL TOXICOLOGY
   13.2 Animal Toxicology and/or Pharmacology

APPROVAL & LABELING

We have completed our review of these supplemental applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

WAIVER OF HIGHLIGHTS SECTION

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling (text for the package insert, Medication Guide), with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Stacy Barley, Senior Regulatory Project Manager, at (301) 796-2137.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
02/25/2014