DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 19-810/S-088
NDA 22-056/S-003

SUPPLEMENT APPROVAL

AstraZeneca
Attention: Judy W. Firor
Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Ms. Firor:

Please refer to your supplemental new drug applications dated and received September 3, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug	NDA #	Supplement #
Prilosec (omeprazole) Delayed-Release Capsules	19-810	088
Prilosec (omeprazole magnesium) For Delayed-Release Oral Suspension	22-056	003

We acknowledge receipt of your submissions dated January 6, 2010.

These "Prior Approval" supplemental new drug applications provide for the following changes to the package insert (PI):

- Drug Interactions section: add information regarding the drug-drug interaction of omeprazole (a CYP 2C19 inhibitor) and cilostazole (metabolized by CYP 2C19)
- Clinical Pharmacology section: add information regarding *Clostridium difficile* infections in hospitalized patients taking omeprazole
- Add to/revise the Warnings and Precautions section of Highlights
- Condense Highlights, and other administrative revisions

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. For administrative purposes, please designate this submission, "SPL for approved NDA 19-810/S-088 and NDA 22-056/S-003".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

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

Enclosures: Package Insert

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22056	SUPPL-3	ASTRAZENECA LP	PRILOSEC FOR DELAYED-RELEASE ORAL SUSP
NDA-19810	SUPPL-88	ASTRAZENECA LP	PRILOSEC DELAYED-RELEASED CAPSULES

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
03/03/2010