



NDA 19-810/S-085

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

Dear Ms. Firor:

Please refer to your supplemental new drug application dated October 25, 2006, received October 25, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec (omeprazole magnesium) Delayed-Release Capsules.

This "Changes Being Effected" supplemental new drug application provides for revisions to the Precautions section, Drug Interactions subsection of the package insert.

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert)

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 19-810/S-085.**" Approval of this submission by FDA is not required before the labeling is used.

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

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Ryan Barraco, Regulatory Project Manager, at (301) 796-0846.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Acting Director
Division of Gastroenterology
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joyce Korvick
4/27/2007 01:19:03 PM