DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-810/S-084

AstraZeneca
Attention: Kelley Davis
Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19801-8355

Dear Ms Davis:

Please refer to your supplemental new drug application dated March 28, 2006, received March 30, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec® (omeprazole) Delayed-Release Capsules.

This supplemental new drug application provides for refined language to the PRECAUTIONS section, Drug Interactions subsection based on additional literature you have provided regarding the interaction between omeprazole and atazanavir.

We completed our review of this application, and it is approved, effective on the date of this letter, for use as recommended in the enclosed labeling text.

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).

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

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastroenterology Products
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/

Brian Harvey
9/25/2006 04:16:59 PM