DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-153/S-031, NDA 21-957/S-003, NDA 22-101/S-001

AstraZeneca LP
Attention: George A. Kummeth
Senior Director, Regulatory Affairs
1800 Concord Pike
P.O. Box 8355
Wilmington, DE 19803

Dear Mr. Kummeth:

Please refer to your supplemental new drug applications dated May 22, 2008, received May 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nexium (esomeprazole magnesium) for Delayed-Release Capsules and Delayed-Release Oral Suspensions.

We acknowledge receipt of your submissions dated May 22, 2008, December 18, 2008 and December 22, 2008.

These "Changes Being Effected" supplemental new drug applications provide for:

- addition of gastrointestinal microbial ecology effects to the Clinical Pharmacology section
- addition of antiretroviral drug information to the Highlights, Drug Interactions and Patient Information sections
- Added heading: *Antiretroviral Agents* and text to be consistent with the Prilosec label approved on December 1, 2008

We completed our review of these applications, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions indicated in the enclosed labeling, as discussed with Mr. George Kummeth on January 8, 2009. The annotated editorial revision is reflective of an inadvertent omission in the December 22, 2008, submission incorporating consistent antiretroviral data from the Prilosec label in the *Antiretroviral Agents* subsection.

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)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that includes the minor editorial revisions indicated in the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-689."

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 an electronic copy of the letter to both this NDA and to the following address:

MEDWATCH
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Chantal Phillips, Regulatory Project Manager, at (301) 796-2259.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Labeling

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

/s/

Donna Griebel

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