DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

NDA 021153/S-036
NDA 021957/S-009
NDA 022101/S-006

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 June 23, 2010 and received June 23, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium (esomeprazole magnesium) Delayed-Release Capsules; Nexium (esomeprazole magnesium) for Delayed Release Oral Suspension, 20 mg and 40 mg; and Nexium (esomeprazole magnesium) For Delayed-Release Oral Suspension, 10 mg.

We acknowledge receipt of your submissions dated August 18 and August 27, 2010.

Reference is also made to our letter dated May 25, 2010 notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for the proton pump inhibitors (PPIs). This information pertains to the risk of osteoporosis-related bone fractures in patients taking proton pump inhibitors for an extended period of time and at high doses.

This supplemental new drug application provides for revisions to the full prescribing information and patient labeling for Nexium. This includes the following addition to the Warnings and Precautions section:

WARNINGS AND PRECAUTIONS:

Several published observational studies suggest that proton pump inhibitor (PPI) therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to the established treatment guidelines. [See Dosage and Administration (2) and Adverse Reactions (6.3)]

In addition, this supplemental new drug application provides for revised language regarding bone fractures to the **Highlights, Table of Contents, Adverse Reactions**, and **Patient Counseling Information** sections of the package insert.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm, that is identical to the enclosed labeling and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements. The SPL will be accessible from publicly available labeling repositories.

We request that the revised labeling approved today be available on your website within 10 days of receipt of this letter.

Also within 14 days, amend all pending supplemental applications for this NDA, including pending "Changes Being Effected" (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.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety information that appears in the revised package labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4) to the address above or by fax to 301-847-8444.

If you have any questions, call Maureen Dewey, at (301) 796-0845.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-22101	SUPPL-6	ASTRAZENECA LP	NEXIUM
NDA-21957	SUPPL-9	ASTRAZENECA LP	NEXIUM DELAYED-RELEASE GRANULES FOR ORAL
NDA-21153	SUPPL-36	ASTRAZENECA LP	NEXIUM 20/40MG DELAYED RELEASE CAPSULES

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/s/

JOYCE A KORVICK
09/03/2010