DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 22-101/S-007
NDA 21-153/S-038
NDA 21-957/S-010
NDA 21-689/S-020

SUPPLEMENT APPROVAL

AstraZeneca LP
Attention: Mark DeSiato
Executive Director, Regulatory Affairs
1800 Concord Pike PO Box 8355
Wilmington, DE 19803-8355

Dear Mr. DeSiato:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received August 5, 2010, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

Drug	NDA#	Supplement#
NEXIUM (esomeprazole magnesium) For Delayed-Release Oral Suspension	22-101	S-007
NEXIUM (esomeprazole magnesium) Delayed-Release Capsules	21-153	S-038
NEXIUM (esomeprazole magnesium) For Delayed-Release Oral Suspension	21-957	S-010
NEXIUM (esomeprazole sodium) For Injection	21-689	S-020

We acknowledge receipt of your amendments dated June 23, May 26, and March 24, 2011, and September 17, 2010.

These "Prior Approval" supplemental new drug applications provide for the following changes:
Package Insert

- Update the Warning and Precautions (5) section with information regarding interactions with diagnostic investigations for neuroendocrine tumors, and concomitant use with St. John's Wort or rifampin
- Update the Drug Interactions (7) section with information regarding interactions with diagnostic investigations for neuroendocrine tumors, and concomitant use with tacrolimus, digoxin, and St. John's Wort or rifampin
- Update the Clinical Pharmacology (12) section with information regarding interactions with diagnostic investigations for neuroendocrine tumors

Patient Package Insert (oral only)

- Update the "What Should I Tell my Doctor Before Taking Nexium" section with the addition of St. John's Wort (Hypericum perforatum) and Rifampin to the medication list

We have completed our review of these supplemental 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, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the package insert(s) 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

You must submit final promotional materials and package insert(s), accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html; instructions are provided on 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.

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.

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

ENCLOSURE: Content of Labeling

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
06/30/2011