DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21-153/S-033
NDA 22-101/S-003

SUPPLEMENT APPROVAL

AstraZeneca
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 application dated July 7, 2009, received July 7, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Nexium (esomeprazole magnesium) Delayed-Release Capsules, 20 mg & 40 mg and Nexium(esomeprazole magnesium) For Delayed-Release Oral Suspension, 10 mg, 20 mg, & 40 mg.

We acknowledge receipt of your submissions dated July 15, 2009; August 12, 2009; September 30, 2009; and October 2, 2009.

These "Changes Being Effected (CBE)" supplemental new drug applications provide for changes reflecting the current language recently approved under NDA 21-957/S005. These CBEs were submitted, as recommended by the Division to cross reference all labels referencing the Nexium oral formulations.

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed, agreed upon labeling text, which is identical to the content of labeling [21 CFR 314.50(l)(1)(i)] in structured product labeling (SPL) format submitted on October 2, 2009.

Within 14 days from the date of this letter, please 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 structured product labeling (SPL) format that includes the changes approved in this supplemental application.

If you have any questions, call Anna Simon, Regulatory Project Manager, at (301) 796-3509.

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
Content of Labeling

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-21153	SUPPL-33	ASTRAZENECA LP	NEXIUM 20/40MG DELAYED RELEASE CAPSULES
NDA-22101	SUPPL-3	ASTRAZENECA LP	NEXIUM

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/s/

DONNA J GRIEBEL
10/09/2009