



NDA 21-153/S025

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

Dear Mr. Kummeth:

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 NEXIUM® (esomeprazole magnesium) Delayed – Release Capsules 20 mg and 40 mg.

This “Prior Approval” supplemental new drug application provides for revisions to the **PRECAUTIONS, Drug Interactions** section of the package insert.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert). Please note that FPL for this supplement should contain all currently approved changes.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission “**FPL for approved NDA 21-153/S-025.**” Approval of this submission by FDA is not required before the labeling is used.

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 Marlene G. Swider, Regulatory Project Manager, at (301) 796-2104.

Sincerely,

*{See appended electronic signature page}*

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

Enclosure

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**This is a representation of an electronic record that was signed electronically and  
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/s/

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Joyce Korvick  
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