



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-153/S-020

Astra Zeneca LP
Wilmington, DE 19803-8355
Attention: George 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 December 3, 2004, received December 6, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nexium[®] (esomeprazole magnesium) Delayed-Release Capsules.

In addition, we acknowledge receipt of your submission dated June 6, 2005.

This supplemental new drug application provides for changes to the **Adverse Reactions, Postmarketing Reports** section of the Nexium[®] package insert.

We completed our review of this application, and it 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) and submitted labeling (package insert submitted June 6, 2005). The Agency notes that your package insert will not be identical to your June 6, 2005 submission until the printing of your next label, which will occur in the next 6-8 weeks.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 21-153/S-020." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

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 a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

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, Melissa Hancock Furness, Regulatory Health Project Manager, at (301) 827-7450.

Sincerely,

{ See appended electronic signature page }

Brian Harvey, M.D., Ph.D.
Director
Division of Gastrointestinal & Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

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

/s/

Joyce Korvick
6/6/05 05:27:58 PM
for Dr. Brian E Harvey