DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-957/S-005

AstraZeneca
Attention: George Kummeth
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 December 18, 2008, received December 18, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nexium (esomeprazole magnesium) for Delayed Release Oral Suspension.

We acknowledge receipt of your submissions dated February 3, 12, 13, & 16, 2009; March 4, 11, & 23, 2009; April 9, 16 & 17, 2009; May 18, 2009, and June 17 & 18, 2009.

This supplemental new drug application provides efficacy, safety, pharmacokinetic, and pharmacodynamic data from studies conducted in infants ages birth to 11 months, inclusive, with gastroesophageal reflux disease (GERD).

We completed our review of this application, as amended. This supplement does not support the use of Nexium in patients less than one year of age with GERD. This application is approved, effective on the date of this letter. However, the agreed-upon labeling changes reflect the lack of efficacy in this patient population.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert, text for the patient package insert). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-957/S005." You must also submit labeling supplements to NDA 21-153 and NDA 22-101, reflecting the current language in this recently approved label. In addition, please submit labeling amendments to your currently pending sNDA's (b) (4) .

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:

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

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
Food and Drug Administration
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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 Chantal Phillips, Regulatory Project Manager, at (301) 796-2259.

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

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

/s/

Donna Griebel

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