DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-957

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

Dear Mr. Kummeth:

Please refer to your new drug application (NDA) dated December 22, 2005, received December 22, 2005, submitted under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act for NEXIUM® for Delayed Release Oral Suspension, 20 and 40 mgs.

We acknowledge receipt of your submissions dated December 22, 2005; and April 17, 2006; April 20, 2006; July 11, 2006; July 13, 2006; August 23, 2006; September 6, 2006; September 7, 2006; October 10, 2006; October 13, 2006; and October 17, 2006.

This new drug application provides for the use of NEXIUM® for Delayed Release Oral Suspension for treatment of Gastroesophageal Reflux Disease (GERD): Healing of Erosive Esophagitis, Maintenance of Healing of Erosive Esophagitis, Symptomatic Gastroesophageal Reflux Disease; Risk Reduction of NSAID-Associated Gastric Ulcer; *H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence; and Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome.

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

Submit content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at http://www.fda.gov/oc/datacouncil/spl.html, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for posting on the DailyMed website.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) and labeling for immediate container and carton labels submitted on December 22, 2005. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 21-957**." Approval of this submission by FDA is not required before the labeling is used.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for the following indications in this application: Risk reduction of NSAID- Associated Gastric Ulcer; *H. pylori* Eradication to Reduce the Risk of Duodenal Ulcer Recurrence; and Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome.

We are deferring pediatric studies (Birth – 11 years) for Gastroesophageal Reflux Disease (GERD): Healing of Erosive Esophagitis, Maintenance of Healing of Erosive Esophagitis, Symptomatic Gastroesophageal Reflux Disease for this application. Pediatric studies (ages 12 – 17) for this indication have been already completed.

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 the Division of Gastroenterology Products 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

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

Sincerely,

{See appended electronic signature page}

Joyce A. Korvick, M.D., M.P.H.
Deputy 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/

Brian Harvey
10/24/2006 05:10:20 PM
For Dr. Joyce Korvick