DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-056 **NDA APPROVAL**

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

Dear Mr. Kummeth:

Please refer to your new drug application (NDA) dated December 20, 2006, received December 20, 2006 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec (omeprazole) for Delayed-Release Oral Suspension.

We acknowledge receipt of your submissions dated December 13, 2007, January 14, 2008, February 28, 2008, and March 18, 2008.

The January 14, 2008 submission constituted a complete response to our October 19, 2007 action letter.

This new drug application provides for the use of Prilosec (omeprazole) for Delayed-Release Oral Suspension for the short term treatment of symptomatic GERD and healing of erosive esophagitis in pediatric patients 1 to 2 years old.

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 and with the editorial revisions listed below:

- In the "FULL PRESCRIBING INFORMATION" section 14.6 "Pediatric GERD", please correct the formatting of the reference at the end of paragraph 1. The phrase "See Use in Specific Populations (8.4)" should be italicized as follows: " [*See Use in Specific Populations (8.4)*]"
- Please correct Table 5 to be consistent with previous versions of this label:

Table 5

Clarithromycin MIC (µg/mL) [a]	Interpretation
≤ 0.25	Susceptible (S)
0.5	Intermediate (I)
> 1.0	Resistant (R)

Amoxicillin MIC (µg/mL) [a,b]	Interpretation
≤0.25	Susceptible (S)

CONTENT OF LABELING

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(l)] 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). 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 22-056."

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and container labels that are identical to the December 13, 2007 submitted carton and immediate container labels as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005)*. Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-056**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

PEDIATRIC RESEARCH EQUITY ACT (PREA)

All applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable. We note that you have fulfilled the pediatric study requirement for ages 1 to 2 years for this application. We are deferring submission of your pediatric study for ages Birth to 1 year for this application because the drug product is ready for approval for use in other age groups and the additional pediatric study has not been completed.

Your deferred pediatric study required by section 505B(a) of the Food, Drug, and Cosmetic Act is a required postmarketing study commitment. The status of this postmarketing study must be reported annually according to 21 CFR 314.81 and section 505B(a)(3)(B) of the Food, Drug, and Cosmetic Act. This commitment is listed below.

1. Deferred pediatric study under PREA for the treatment of Gastrointestinal Esophageal Reflux Disease (GERD) and Erosive Esophagitis in pediatric patients ages Birth to 1 year.

   Final Report Submission: December 31, 2010

Submit final study reports to this NDA. For administrative purposes, all submissions related to this pediatric postmarketing study commitment must be clearly designated "**Required Pediatric Study Commitments**".

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the

proposed materials in draft or mock-up form with annotated references, and the package insert(s) 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

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

METHODS VALIDATION

We have not completed validation of the regulatory methods. However, we expect your continued cooperation to resolve any problems that may be identified.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
HFD-001, Suite 5100
5515 Security Lane
Rockville, MD 20852

REPORTING REQUIREMENTS

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 Elizabeth Ford, Regulatory Project Manager, at (301) 796-0193.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Package Insert Label

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

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