DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-810/S-087
NDA 22-056/S-001

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

Dear Mr. Kummeth:

Please refer to your supplemental new drug applications dated May 22, 2008, received on May 22, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Prilosec (omeprazole) Delayed-Release Capsules, 10mg, 20mg, and 40 mg; and Prilosec (omeprazole magnesium) For Delayed-Release Oral Suspension, 2.5mg or 10 mg.

These "Changes Being Effected" supplemental new drug applications provide for the following changes: Section 7 **Drug Interactions** incorporation of new information regarding the interaction of omeprazole with antiretroviral drugs (a drug-drug interaction) and Section 12.4 **Effects of Gastrointestinal Microbial Ecology** to include information regarding omeprazole and GI bacteria.

We completed our review of these applications, as amended. These applications are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the editorial revisions listed below:

Highlight: Drug Interactions:

A statement of "Saquinavir: PRILOSEC may increase plasma levels of saquinavir (7)" should be added.

Section 7 Drug Interactions:

The Atazanavir subsection should be renamed as Antiretroviral Agents.

A statement of "Following multiple doses of nelfinavir (1250 mg, bid) and omeprazole (40 mg, qd), AUC was decreased by 36% and 92 %, Cmax by 37% and 89% and Cmin by 39% and 75% respectively for nelfinavir and M8." followed by a statement of "Following multiple doses of atazanavir (400mg qd) and omeprazole (40 mg, qd, 2 hr before atazanavir), AUC was decreased by 94%, Cmax by 96%, and Cmin by 95%." should be added after the statement of "For some antiretroviral drugs, such as atazanavir and nelfinavir, decreased serum levels have been reported when given together with omeprazole."

Also, the statement of "For other antiretroviral drugs, such as saquinavir, elevated serum levels have been reported." should be revised to "For other antiretroviral drugs, such as saquinavir, elevated serum levels have been reported with an increase in AUC by 82%, in Cmax by 75% and in Cmin by 106% following multiple dosing of saquinavir/ritonavir (1000/100 mg) bid for 15 days with omeprazole 40 mg qd co-administered days 11 to 15. Dose reduction of saquinavir should be considered from the safety perspective for individual patients."

The changes above were shared with Ms. Kelly Davis, Associate Director for Labeling at Astra Zeneca. Ms. Davis and her staff accepted all these changes as proposed.

Within 21 days of the date of this letter, submit 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 in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of Medicine for public dissemination.

In addition, submit three copies of the introductory promotional materials that you propose to use for these products. 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
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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}

Donna J. Griebel, M.D.
Director,
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Attachment

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

/s/

Ruyi He

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