DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-987/S-035
NDA 20-988/S-038

Wyeth Pharmaceuticals Inc.
Attention: Joanne Palmisano, MD, FACP
Assistant Vice President
Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Palmisano:

Please refer to your supplemental new drug applications dated October 15, 2007 (NDA 20-987/S-035) and May 4, 2007 (NDA 20-988/S-038), received October 15, 2007 and May 4, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix® (pantoprazole sodium) Delayed-Release Tablets and Protonix® I.V. (pantoprazole sodium) for Injection.

We acknowledge receipt of your submissions dated December 3, 2007 (NDA 20-987/S-035) and December 13, 2007 (NDA 20-988/S-038).

These "Changes Being Effected" supplemental new drug applications provide for updates to the safety information in **PRECAUTIONS/Drug Interactions** subsections to include the following statement:

> Concomitant use of atazanavir and proton pump inhibitors is not recommended. Coadministration of atazanavir with proton pump inhibitors is expected to substantially decrease atazanavir plasma concentrations and thereby reduce its therapeutic effect.

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.

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 to the submitted labeling dated December 3, 2007 (NDA 20-987/S-035) and December 13, 2007 (NDA 20-988/S-038). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate these submissions: "SPL for approved supplement NDA 20-987/S-035" and "SPL for approved supplement NDA 20-988/S-038" respectively.

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/ the Division of Gastroenterology Products and two copies of both the promotional materials and the package inserts 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 Elizabeth Ford, R.N., Regulatory Project Manager, at (301) 796-0193.

Sincerely,

{See appended electronic signature page}

Dan Shames, M.D.
Acting Director
Division of Gastroenterology Products
Office of Drug Evaluation III

Enclosures (2)

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

/s/

Daniel A. Shames
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