DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-987/S-021

Wyeth Pharmaceuticals Inc.
Attention: Diane Mitrione
Assistant Vice-President, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Ms. Mitrione:

Please refer to your supplemental new drug application dated July 22, 2003, received July 23, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix® (pantoprazole) Delayed-Release Tablets.

We acknowledge receipt of your submission dated July 29, 2003.

This "Changes Being Effected" supplemental new drug application provides for multiple revisions to the **CLINICAL PHARMACOLOGY/ Pharamcokinetics/*Special Populations/*** *Hepatic Impairment*, **DOSAGE AND ADMINISTRATION**, **PRECAUTIONS/General** , and **ADVERSE REACTIONS/ Postmarketing Reports** sections of the package insert.

We completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 22, 2003.

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, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susan Daugherty, Consumer Safety Officer, at (301) 827-7456.

Sincerely,

{See appended electronic signature page}

Robert L. Justice, M.D., M.S.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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
12/30/03 09:17:49 AM
for Dr. Robert Justice