DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-988/S-031

Wyeth Pharmaceuticals
Attention: Joanne Palmisano, M.D., F.A.C.P.
Assistant Vice President, Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Palmisano:

Please refer to your supplemental new drug application dated March 23, 2005, received March 24, 2005; under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Protonix® I.V. (pantoprazole sodium) for Injection.

We acknowledge receipt of your submissions dated July 12th and July 19, 2005.

This "Changes Being Effected" supplemental new drug application provides for revisions in the text of the physician's package insert to update the safety information under the **ADVERSE REACTIONS Safety Experience with Oral Pantoprazole** section.

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

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert), and your submitted labeling (package insert) submitted July 12, 2005.

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 supplement NDA 20-988/S-031**." Approval of this submission by FDA is not required before the labeling is used.

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 Mary Lewis, Regulatory Project Manager, at (301) 827-7475

Sincerely,

{See appended electronic signature page}

Brian E. Harvey, M.D., Ph.D.
Director
Division of Gastrointestinal and
Coagulation Drug Products
Office of Drug Evaluation III, HFD-180
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
8/2/05 04:37:53 PM