DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-988/S-032

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

Dear Dr. Palmisano:

Please refer to your supplemental new drug application dated March 31, 2005, received April 4, 2005 submitted under section 505 (b) of the Food, Drug and Cosmetic Act for Protonix® I.V. (pantoprazole sodium) for Injection.

We acknowledge receipt of your submissions dated April 28, 2005 and July 19, 2005.

This supplemental new drug application provides for extending the reconstituted time in the vial to 6 hours and 18 hours when admixed for a total of 24 hours, or up to 24 hours reconstituted in the vial for use as a two-minute infusion.

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 submitted labeling (package insert submitted July 22, 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-032.** Approval of this submission by FDA is not required before the labeling is used.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Mary Lewis, Regulator 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
8/3/05 04:09:55 PM