DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-988/S-016

Wyeth Pharmaceuticals, Inc.
Attention: Caroline Henesey, Ph.D.
Senior Manager, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Henesey:

Please refer to your supplemental new drug application dated April 28, 2003, received April 25, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix® I.V. (pantoprazole sodium) for Injection.

This supplemental new drug application provides for a two-minute infusion dosing regimen for Protonix® I.V.

We acknowledge receipt of your faxed submission dated October 24, 2003, containing your agreement to make the changes below.

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

1. In the **Treatment of Gastroesophageal Reflux Disease Associated with a History of Erosive Esophagitis** subsection of the **DOSAGE AND ADMINISTRATION** section make the following change (deletions are shown as ~~strikeouts~~ and additions are shown as double underlines):

   "Two Minute Infusion

   PROTONIX I.V. for Injection should be reconstituted with 10 mL of 0.9% Sodium Chloride Injection, USP, to a final concentration of approximately 4 mg/mL. The reconstituted solution may be stored for up to 2 hours at room temperature prior to intravenous infusion and does not need to be protected from light. PROTONIX I.V. for Injection should be administered intravenously over a period of ~~(b)(4) ---------~~ at least 2 minutes using the filter provided."

2. In the **Pathological Hypersecretion Associated with Zollinger-Ellison Syndrome** subsection of the **DOSAGE AND ADMINISTRATION** section make the following change (deletions are shown as ~~strikeouts~~ and additions are shown as double underlines):

"Two Minute Infusion

PROTONIX I.V. for Injection should be reconstituted with 10 mL of 0.9% Sodium Chloride Injection, USP, to a final concentration of approximately 4 mg/mL. The reconstituted solution may be stored for up to 2 hours at room temperature prior to intravenous infusion and does not need to be protected from light. PROTONIX I.V. for Injection should be administered intravenously over a period of ~~(b)(4) ---------~~ at least 2 minutes using the filter provided."

The final printed labeling (FPL) must be identical to the submitted labeling (package insert submitted April 25, 2003) except for the revisions indicated above. These revisions are terms of the approval of this application.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 20-988/S-016." 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 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/

Robert Justice

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