



NDA 20-988/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 new drug application (NDA) dated July 29, 2003, received July 30, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix<sup>®</sup> I.V. (pantoprazole sodium) for Injection.

This "Changes Being Effected" supplemental new drug application provides for the addition of "elevated CPK (creatine phosphokinase)" to the **Postmarketing** subsection under the **ADVERSE REACTIONS** section of the package insert (PI).

We completed our review of this application and it is approved for use as submitted in the PI labeling text, effective on the date of this letter.

We cannot accept the final printed labeling (FPL) submitted with this supplemental new drug application, as it does not contain the changes approved under NDA 20-988/S-016 on October 24, 2003. FPL for NDA 20-988/S-016 was submitted on November 19, 2003, received November 20, 2003, and supercedes the FPL submitted for NDA 20-988/S-021.

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

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/s/

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Joyce Korvick  
1/2/04 09:03:32 AM  
for Dr Robert Justice