



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

NDA 20-988/S-028

Wyeth Pharmaceuticals, Inc.  
Attention: Caroline Henesey Ph.D.  
Associate Director, Worldwide Regulatory Affairs  
500 Arcola Road  
Collegeville, PA 19426

Dear Dr. Henesey:

Please refer to your supplemental new drug application dated May 18, 2004, received May 19, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix<sup>®</sup> I.V. (pantoprazole sodium) for Injection.

This supplemental new drug application provides for the reformatting of the **Postmarketing Reports** subsection of the **ADVERSE EVENTS** section of the package insert.

We completed our review of this application. 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 submitted labeling (package insert submitted May 18, 2004).

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-028." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to this division and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, MD 20857

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 Melissa Hancock Furness, Regulatory Health Project Manager, at (301) 827-7450.

Sincerely,

*{See appended electronic signature page}*

Joyce Korvick, M.D., M.P.H.  
Acting Director  
Division of Gastrointestinal & 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  
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