DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 20-988

Wyeth-Ayerst Laboratories
Attention: Diane Mitrione, Assistant Vice President
Worldwide Regulatory Affairs
150-B3 Radnor-Chester Road
St. Davids, PA 19087

Dear Ms. Mitrione:

Please refer to your supplemental new drug application dated August 28, 2001, received August 29, 2001, submitted 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 submission dated August 22, 2002, received August 23, 2002.
Your submission of August 22, 2002, constituted a complete response to our February 25, 2002 action letter.

This "Changes Being Effected" supplemental new drug application provides for revisions in the **CLINICAL PHARMACOLOGY, PRECAUTIONS,** and **DOSAGE AND ADMINISTRATION** sections of the package insert.

We have completed our review of this supplemental new drug application, as amended. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on August 22, 2002.

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, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Susan Daugherty, Consumer Safety Officer, at (301) 827-7475

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/

Joyce Korvick
2/21/03 01:40:18 PM
for Dr. Robert Justice