DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

NDA 22020/S- 014, NDA 20987/S-052, NDA 20988/S-058

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer
Attention: Karen C. Baker, MS
Director, Pfizer Essential Health Global Regulatory Affairs Brands
235 East 42nd Street
New York, NY 10017

Dear Ms. Baker:

Please refer to your Supplemental New Drug Applications (sNDAs) dated and received June 6, 2017, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for:

NDA#	Supplement#	Product Description
022020	S-014	PROTONIX® (pantoprazole sodium) for Delayed-Release Oral Suspension, 40 mg
020987	S-052	PROTONIX® (pantoprazole sodium) Delayed-Release Tablets, 20 mg and 40 mg
020988	S-058	PROTONIX® I.V. (pantoprazole sodium) for Injection

These Prior Approval supplemental new drug applications provide for revision to the carton/container labeling to add equivalency statement to indicate the amount of active moiety related to the amount of active ingredient (salt) for the above referenced drug products.

APPROVAL & LABELING

We have completed our review of these supplemental applications. They are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the following minor editorial revisions to be implemented in the next printing:

A. NDA 22020 Container (packet) Label

a. Provide updated container labels with a space reserved for the Lot Number and Expiration date per 21 CFR 201.10(i)(1) and 21 CFR 201.17.

B. NDA 20988 Carton and Container Labels and Labeling

a. We recommend revising the route of administration statement "For I.V. infusion only" to "For Intravenous Infusion Only." Furthermore, revise any other abbreviation "I.V." to "Intravenous," on the container label and carton labeling (not including the I.V. in the proprietary name). Dangerous abbreviations, symbols, and dose designations are included in the Institute of Safe Medication Practice's List of Error-prone Abbreviations, Symbols, and Dose Designations. As part of a national campaign to avoid the use of dangerous abbreviations and dose designations, FDA agreed not to approve such error prone abbreviations in the approve labeling of products.

b. We recommend adding the statement "Single-dose vial"" to the PDP, below the route of administration statement to provide information on the appropriate use of this product.

C. NDA 20987 Container Labels

a. We recommend adding the statement "**Swallow tablets whole**. Do NOT split, chew, or crush tablets." to the Principal Display Panel to emphasize the safe and proper use of this product.

CARTON AND IMMEDIATE CONTAINER LABELS

Submit final printed carton and immediate container labels that are identical to the submitted carton and immediate container labels, except with the revisions listed above, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (May 2015, Revision 3)*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 20987/S-052, NDA 22020/S- 014, NDA 20988/S-058.**" Approval of these submissions by FDA is not required before the labeling is used.

REPORTING REQUIREMENTS

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 Grecia C. Edwards, Regulatory Business Process Manager, at (240) 402 - 1773.

Sincerely,

{See appended electronic signature page}

David Lewis, PhD.
Acting Branch Chief, BII
Division of Post-Marketing Activities I
Office of Lifecycle Drug Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:
Carton and Container Labeling

David Lewis

Digitally signed by David Lewis
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