DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20987/S-051
NDA 20988/S-055
NDA 22020/S-013

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.
Attention: Karen Baker
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 February 21, 2017, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA	Supplement	Drug Product
20987	S-051	Protonix (pantoprazole sodium) delayed-release tablets
20988	S-055	Protonix I.V. (pantoprazole sodium) for injection
22020	S-013	Protonix (pantoprazole sodium) delayed-release oral suspension

These "Changes Being Effected supplemental new drug applications provide for the addition of "Interference with Investigations for Neuroendocrine Tumors" to the Warnings and Precautions section, and updates to reflect the guidance for industry *Naming of Drug Products Containing Salt Drug Substances (June 2015)* in the prescribing information (PI). Also, content and format in the Medication Guide and Instructions for Use in the Oral PI was updated for consistency across the drug class.

APPROVAL & LABELING

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA

automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling, with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eList may be found in the guidance for industry titled "SPL Standard for Content of Labeling Technical Qs and As" at http://www.fda.gov/downloads/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

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 Heather Buck, Regulatory Project Manager, at (301) 796-1413.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director for Safety
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

ENCLOSURE: Content of Labeling (Oral PI, Medication Guide, IFU; Injection PI)

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

JOYCE A KORVICK
12/20/2017