DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 20987/S-53
NDA 22020/S-15

SUPPLEMENT APPROVAL

Wyeth Pharmaceuticals Inc.,
A subsidiary of Pfizer
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 Application (sNDA) dated June 23, 2017, received, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for PROTONIX (pantoprazole sodium) delayed-release tablets, 20 and 40 mg, PROTONIX (pantoprazole sodium) for delayed-release oral suspension, 40 mg.

We also refer to our letter dated March 7, 2017, notifying you, under Section 505(o)(4) of the FDCA, of new safety information that we believe should be included in the labeling for PROTONIX (pantoprazole sodium) delayed-release tablets, 20 and 40 mg, PROTONIX (pantoprazole sodium) for delayed-release oral suspension, 40 mg. This information pertains to the risk of changes in bone morphology observed in offspring of rats that were exposed to pantoprazole *in utero* and through milk, during the period of lactation, as well as postnatal oral dosing with the use of the PROTONIX, based on new safety information about this risk identified since the product was approved.

This supplemental new drug application provides for revisions to the labeling for PROTONIX (pantoprazole sodium) delayed-release tablets, 20 and 40 mg, PROTONIX (pantoprazole sodium) for delayed-release oral suspension, 40 mg, consistent with our March 7, 2017.

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.

We note that your June 23, 2017, submission includes final printed labeling (FPL) for your package insert and medication guide. We have not reviewed this FPL. You are responsible for

assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

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 (text for the package insert and medication guide), 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 Mimi Phan, Regulatory Project Manager, at (301) 796-5408.

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(S):
Content of Labeling
and medication guide

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
07/06/2017