CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

22-020

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 22-020

Wyeth Pharmaceuticals
Attention: Jethro Ekuta, D.V.M., Ph.D.
Director II, Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Ekuta:

Please refer to your new drug application (NDA) dated May 12, 2006, received May 15, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Protonix (pantoprazole sodium), Delayed Release ⊏ ⊐, 40 mg. b(4)

We acknowledge receipt of your submissions dated June 30, July 5, October 13, October 31, November 30, and December 20, 2006, and February 16, February 28, and March 15, 2007.

We completed our review and find the information presented is inadequate. Therefore, the application is approvable. The deficiencies are summarized as follows:

> An FDA Division of Scientific Investigations (DSI) audit of the ⊏ ⊐ facility conducting the pharmacodynamic (PD) comparability study titled "A Randomized, 2-Period, Crossover, Pharmacodynamic Comparability Study Comparing a Pantoprozole Sodium Spheriod Formulation to the Currently Marketed Tablet Formulation in Subjects with GERD and a History of Erosive Esophagitis" (3001-B1-332-US) has found that the analytical data for the PD endpoint in this study are not acceptable for review, because of insufficient method validation, calibration, quality control, and documentation. Therefore, data from this PD study cannot be used to support this NDA. Without valid PD comparability data, or data demonstrating bioequivalence to the reference listed product, the safety and efficacy of Protonix Delayed Release ⊏ ⊐ cannot be determined. If these deficiencies cannot be resolved, you will need to perform an additional PD study to support an approval of your application. b(4)

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.120. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

Under 21 CFR 314.102(d), you may request a meeting or telephone conference with this division to discuss what steps need to be taken before the application may be approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, contact Thomas Moreno, Regulatory Project Manager, at (301) 796-2247.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.P.H.
Deputy Director
Division of Gastroenterology 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
3/15/2007 05:07:10 PM