DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 22-020 **NDA APPROVAL**

Wyeth Pharmaceuticals, Inc.
Attention: Joanne Palmisano, M.D.
Assistant Vice President
Global Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Palmisano:

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) For Delayed-Release Oral Suspension.

We acknowledge receipt of your submissions dated May 15, August 1, November 5, and November 14, 2007.

The August 1, 2007 submission constituted a complete response to our March 15, 2007 action letter.

This new drug application provides for the use of Protonix (pantoprazole sodium) For Delayed-Release Oral Suspension for: Short-Term Treatment of Erosive Esophagitis Associated With Gastroesophageal Reflux Disease (GERD); Maintenance of Healing of Erosive Esophagitis; and Pathological Hypersecretory Conditions Including Zollinger-Ellison Syndrome.

We have completed our review of this 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, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling (text for the package insert) and/or submitted labeling (package insert submitted November 14, 2007. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 22-020."

Submit final printed carton and container labels that are identical to the carton and immediate container labels submitted November 14, 2007 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 titled *Providing Regulatory Submissions in Electronic Format – Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications (October 2005).* Alternatively, you may submit 12 paper copies, with 6 of the copies individually mounted on heavy-weight paper or similar material. For administrative purposes, designate this submission "**Final Printed Carton and Container Labels for approved NDA 22-020**." Approval of this submission by FDA is not required before the labeling is used.

Marketing the product(s) with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

All applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred. We are waiving the pediatric study requirement for ages birth to seventeen years for the treatment of pathological hypersecretory conditions including Zollinger-Ellison syndrome and deferring pediatric studies for ages birth to seventeen years for short-term treatment of erosive esophagitis associated with gastroesophageal reflux disease and for maintenance of healing of erosive esophagitis in this application.

Your deferred pediatric studies required under section 2 of the Pediatric Research Equity Act (PREA) are considered required postmarketing study commitments. The statuses of these postmarketing studies shall be reported annually according to 21 CFR 314.81. These commitments are listed below.

1. Deferred pediatric study under PREA for the treatment of erosive esophagitis associated with gastroesophageal reflux disease in pediatric patients ages birth to seventeen years.

   Final Report Submission: December 31, 2008

2. Deferred pediatric study under PREA for the maintenance of healing of erosive esophagitis in pediatric patients ages birth to seventeen years.

   Final Report Submission: December 31, 2008

Submit final study reports to this NDA. For administrative purposes, all submissions related to these pediatric postmarketing study commitments must be clearly designated "**Required Pediatric Study Commitments**".

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit, in triplicate, a cover letter requesting advisory comments, the proposed materials in draft or mock-up form with annotated references, and the package insert(s) to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the package insert(s), at the time of initial dissemination or publication, accompanied by a Form FDA 2253. For instruction on completing the Form FDA 2253, see page 2 of the Form. For more information about submission of promotional materials to the Division of Drug Marketing, Advertising, and Communications (DDMAC), see www.fda.gov/cder/ddmac.

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 Brian Strongin, R.Ph., M.B.A., Chief, Regulatory Project Management Staff, at (301) 796-1008.

Sincerely,

{See appended electronic signature page}

Joyce Korvick, M.D., M.Ph.
Deputy Director
Division of Gastroenterology Products
Office of Drug Evaluation III

Enclosure

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

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