DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022020/S-002
NDA 020987/S-036
NDA 020987/S-037

APPROVAL LETTER

Wyeth Pharmaceuticals
Attention: Nia Tatsis, Ph.D.
Manager, Global Regulatory Affairs
500 Arcola Road
Collegeville, PA 19426

Dear Dr. Tatsis:

Please refer to your supplemental new drug applications dated November 21, 2008, May 12, 2009 and May 13, 2009, received November 21, 2008, May 12, 2009 and May 13, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PROTONIX (pantoprazole sodium) For Delayed-Release Oral Suspension 40 mg, and PROTONIX (pantoprazole sodium) Delayed-Release Tablet, 20 mg and 40 mg.

We acknowledge receipt of your submissions dated February 6, 2009, February 19, 2009, March 6, 2009, April 3, 2009, April 14, 2009, May 20, 2009, May 26, 2009, July 2, 2009, July 22, 2009, October 19, 2009 and October 22, 2009.

These prior approval supplemental new drug applications provide for the use of PROTONIX (pantoprazole sodium) For Delayed-Release Oral Suspension 40 mg (NDA 022020/S-002), and PROTONIX (pantoprazole sodium) Delayed-Release Tablet, 20 mg and 40 mg (NDA 020987/S-036 and S-037) for the short term treatment of erosive esophagitis associated with GERD in pediatric patients ages five years and older. The applications also provide for revisions to the package insert to include clinical and pharmacokinetic data from studies in pediatric patients birth through five years of age.

We completed our review of these supplemental new drug applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text and with the minor editorial revisions listed below.

- Remove the bold text format from the subheadings within sections 2.2, 8.1,12.2, 13.2 and 14.1.

We note that you do not intend to market PROTONIX (pantoprazole sodium) For Delayed-Release Oral Suspension in smaller dosage strengths, which would be the age appropriate formulation in pediatric patients under five years of age. Under the Best Pharmaceuticals for

Children Act (BPCA) (21 U.S.C. 355a), FDA will publish a notice identifying any drug for which, on or after the date of the enactment of the BPCA of 2007, a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population (or specified subpopulation) that is not introduced onto the market. Such an action will be taken if the pediatric formulation for this drug is not marketed within one year of our public notification granting exclusivity on February 26, 2009.

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)(1)(i)] 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. For administrative purposes, please designate this submission, "SPL for approved NDA 022020/S-002; NDA 020987/S-036 and S-037."

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

There is no pediatric study requirement for these applications because they do not involve a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration.

This submission responded to the following postmarketing study requirements for NDA 022020:

1. Deferred pediatric study under PREA for the treatment of erosive esophagitis associated with gastroesophageal reflux disease in pediatric patients ages birth to 17 years.

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

We will notify you regarding the final status of these PREA commitments in a separate letter.

PROMOTIONAL MATERIALS

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 http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm.

LETTERS TO HEALTH CARE PROFESSIONALS

If you issue a letter communicating important safety related information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit an electronic copy of the letter to both this NDA and to the following address:

MedWatch
Food and Drug Administration
5600 Fishers Lane, Room 12B05
Rockville, MD 20857

REPORTING REQUIREMENTS

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Roland Girardet, M.H.S., M.S., M.B.A., Regulatory Project Manager, at (301) 796-3827.

Sincerely,

{See appended electronic signature page}

Donna Griebel, M.D.
Director
Division of Gastroenterology Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Application Type/Number	Submission Type/Number	Submitter Name	Product Name
NDA-20987	SUPPL-36	WYETH PHARMACEUTICALS INC	PROTONIX (PANTOPRAZOLE SODIUM) 40MG ENTE
NDA-20987	SUPPL-37	WYETH PHARMACEUTICALS INC	PROTONIX (PANTOPRAZOLE SODIUM) 40MG ENTE
NDA-22020	SUPPL-2	WYETH PHARMACEUTICALS INC	PROTONIX DELAYED RELEASE GRANULES

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

/s/

DONNA J GRIEBEL
11/12/2009