DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

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Wyeth Pharmaceuticals, Inc.
Attention: John J. Savarese, M.D., Ph.D.
Senior Director, Worldwide Regulatory Affairs
P.O. Box 8299
Philadelphia, PA 19101-8299

Dear Dr. Savarese:

Please refer to your correspondence dated May 31, 2002, requesting changes to FDA's December 31, 2001, Written Request for pediatric studies for Protonix®.

We reviewed your proposed changes and are amending the below listed sections of the Written Request. All other terms stated in our original Written Request issued on December 31, 2001, and our amended Written Request issued on December 18, 2002, remain the same.

TYPE OF STUDIES:

STUDY 5: PHARMACOKINETIC, EXPOSURE/ RESPONSE, AND SAFETY STUDY IN PEDIATRIC PATIENTS 1 TO 11 YEARS OF AGE

Pharmacokinetic Component: Part 2 (repeated dose)

This will be a repeated-dose pharmacokinetic and safety study of at least two dose-levels of pantoprazole sodium **for patients 1 to 4 years of age**. Patients will be randomly allocated to treatment groups in approximately equal proportions. The dose level(s) and frequency of dosing used in this part of the study will be selected based on results from Part 1. At least 12 patients (i.e., at least 6 per treatment group) will complete this part of the study if standard PK approach is used. Alternatively, a population PK approach may be used. An open-label design is acceptable.

STUDY 6: PHARMACOKINETIC AND SAFETY STUDY IN PEDIATRIC PATIENTS 12 TO 16 YEARS OF AGE

Pharmacokinetic Component: Part 2 (repeated-dose) **has been deleted**.

Reports of the studies that meet the terms of the Written Request dated December 31, 2001, as amended by this letter must be submitted to the Agency on or before December 31, 2005, in order to possibly qualify for pediatric exclusivity extension under Section 505A of the Act.

Submit protocols for the above studies to an investigational new drug application (IND) and clearly mark your submission, **"PEDIATRIC PROTOCOL SUBMITTED FOR PEDIATRIC**

EXCLUSIVITY STUDY" in large font, bolded type at the beginning of the cover letter of the submission. Notify us as soon as possible if you wish to enter into a written agreement by submitting a proposed written agreement. Please clearly mark your submission, **"PROPOSED WRITTEN AGREEMENT FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission.

Submit reports of the studies as a **supplement to an approved NDA** with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, clearly mark your submission **"SUBMISSION OF PEDIATRIC STUDY REPORTS – PEDIATRIC EXCLUSIVITY DETERMINATION REQUESTED"** in large font, bolded type at the beginning of the cover letter of the submission and include a copy of this letter. In addition, send a copy of the cover letter of your submission, via fax (301-594-0183) or messenger to the Director, Office of Generic Drugs, HFD-600, Metro Park North II, 7500 Standish Place, Rockville, MD 20855-2773.

If you wish to discuss any amendments to this Written Request, submit proposed changes and the reasons for the proposed changes to your application. Clearly mark submissions of proposed changes to this request **"PROPOSED CHANGES IN WRITTEN REQUEST FOR PEDIATRIC STUDIES"** in large font, bolded type at the beginning of the cover letter of the submission. We will notify you in writing if we agree to any changes to this Written Request.

We hope you will fulfill this pediatric study request. We look forward to working with you on this matter in order to develop additional pediatric information that may produce health benefits to the pediatric population.

If you have any questions, call Susan Daugherty, Consumer Safety Officer, at (301) 827-7475.

{See appended electronic signature page}

Julie Beitz, M.D.
Deputy Director
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/

Julie Beitz
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