DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 022020

NOTIFICATION OF NON-COMPLIANCE WITH PREA

Wyeth Pharmaceuticals Inc.
c/o Pfizer, Inc.
Attention: Jonathan (Greg) Carrier
Senior Director, WRS
235 East 42nd Street
New York, NY 10017

Dear Mr. Carrier:

Please refer to your New Drug Application (NDA) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for Protonix (pantoprazole sodium) Delayed-Release Tablets, 20 mg and 40 mg, which was approved on November 14, 2007.

The Agency has determined that you have failed to meet the requirements of the Pediatric Research Equity Act (PREA) for this application because you have not yet submitted your pediatric assessment, which was deferred until December 31, 2008.

Under the provisions of title V, section 505, of the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA), you must respond in writing within forty-five calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response. We note that you requested a deferral extension on January 4, 2013; however, we have determined that your request does not qualify for an extension.

In accordance with FDASIA, FDA will post this letter and your response on the website located at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DevelopmentResources/ucm343203.htm with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDA with a cross-reference letter to the IND to which your protocol has been submitted. In addition, send a copy of the cover letter to CDER's Pediatric and Maternal Health Staff.

If you have any questions, call CDR Stacy Barley, Senior Regulatory Project Manager, at (301) 796-2137.

Sincerely,

{See appended electronic signature page}

Andrew E. Mulberg, M.D., F.A.A.P., C.P.I.
Deputy Director
Division of Gastroenterology and Inborn Errors Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

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/s/

ANDREW E MULBERG
06/14/2013