Worldwide Regulatory Strategy
Pfizer Inc
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Worldwide Research & Development

26 July 2013

Donna Griebel, M.D, Director
Division of Gastroenterology & Inborn Error Products
Food and Drug Administration
Center for Drug Evaluation and Research
c/o Central Document Room
5901-B Ammendale Road
Beltsville, Maryland 20705-1266

Re: NDA 22-020 - Protonix® (pantoprazole sodium) Delayed-Release Suspension

IND 68,011 serial 0519

Postmarketing Commitment 857-2

RESPONSE TO PREA NON-COMPLIANCE LETTER of June 14, 2013

Please refer to the Technical Annex for submission format information

Dear Dr. Griebel:

Reference is made to NDA 22-020 Protonix® (pantoprazole sodium) Delayed-Release Suspension, the corresponding IND 68,011 for this product, and to Postmarketing Requirement 857-2. Reference is also made to FDA's Notification of Non-Compliance with PREA letter of June 14, 2013.

Pfizer's submission of November 21, 2008 provided clinical study data on the pharmacokinetics, efficacy and safety of pantoprazole in pediatric subjects ranging in age from 1 to 16 years who required treatment for erosive esophagitis or gastroesophageal reflux disease (GERD). As noted in FDA's letter of July 13, 2010, FDA found the information provided by these clinical studies insufficient to meet the PREA commitment in that these studies did not address the long-term safety of Protonix use for maintenance of healing of erosive esophagitis in pediatric patients. In a communication to FDA of August 15, 2012, Pfizer proposed a study design it believed to be sufficient to fulfill the outstanding

commitment. FDA responded with an Information Request letter of May 30, 2013, indicating the agency did not agree with Pfizer's proposal. Pfizer's request for a deferral extension of this PREA commitment was denied by FDA in a separate letter of May 30, 2013.

Pfizer is fully committed to fulfilling its post-marketing obligations under PREA and to timely completion of the studies requested by FDA. Draft study protocols will be submitted to FDA within 15 days of the date of this letter.

Should you have any questions regarding this response, please contact me via phone at (423) 989-8166; via facsimile at (423) 990-2566; or via e-mail at Jonathan.Carrier@pfizer.com.

Sincerely,

Jonathan (Greg) Carrier
Worldwide Regulatory Strategy

cc: CDER Pediatric and Maternal Health Staff

Annex - Electronic Submission Technical Information

Submission Sequence Number	0083
Approximate Size of Submission	1 MB
Index/Number of Media Units Per full Set	Gateway
Electronic Media Virus Checking	The submission has been scanned using McAfee VirusScan Enterprise Version 8.8 and is virus free
Technical Point of Contact	Mike Tagliaferi Email: mike.tagliaferi@pfizer.com Tel: (484) 865-5918

US Region Submissions are assembled in compliance with version 2.01 of the US Regional Module 1 Specification and ICH v3.2.2.

All sections of the submission are being filed electronically.