



NOV 14 2005

Food and Drug Administration  
Rockville MD 20857

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Mr. Anthony Celeste  
Senior Vice President  
AAC Consulting Group  
7361 Calhoun Place, Suite 500  
Rockville, MD 20855-2765

Re: Docket No. 2005P-0196

Dear Mr. Celeste:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in the citizen petition that you submitted for Sun Pharmaceutical Industries (SPI) on May 18, 2005, concerning the appropriateness of SPI's submission of an abbreviated new drug application for a proposed generic version of a discontinued form of Wyeth Pharmaceuticals' Protonix I.V. (pantoprazole sodium) for injection. More specifically, SPI seeks a determination that the originally approved and now discontinued formulation of Wyeth Pharmaceuticals' Protonix I.V. was not discontinued for reasons of safety or efficacy, is not less safe or effective than Wyeth's currently marketed product, and is therapeutically equivalent to Wyeth's currently marketed product. SPI also seeks a determination that its generic version of Wyeth's original formulation of Protonix I.V. need not contain the in-line filter, which was part of Wyeth's approved original new drug application.

FDA has been unable to reach a decision on your petition because of the need to address other agency priorities. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as possible given the numerous demands on the Agency's resources.

Sincerely,

Jane A. Axelrad  
Associate Director for Policy  
Center for Drug Evaluation and Research

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