



JUL 18 2005

Food and Drug Administration
Rockville MD 20857

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Marcy Macdonald
Director, Regulatory Affairs
Apotex Corp.
616 Heathrow Drive
Lincolnshire, IL 60069

Re: Docket No. 2005P-0023/CP1

Dear Ms. Macdonald:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated January 13, 2005. Your petition requests that the Agency determine whether the reference listed drug Tequin (gatifloxacin) Injection, 10 mg/mL (200 mg), approved under new drug application (NDA) 21-062 held by Bristol-Myers Squibb, was voluntarily discontinued from sale in the United States for safety or effectiveness reasons.

FDA has been unable to reach a decision on your petition due to 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 request 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

2005P-0023

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