



Food and Drug Administration
Rockville MD 20857

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FEB 10 2006

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

Re: Docket No. 2005P-0023/CP1

Dear Ms. Macdonald:

This letter responds to your citizen petition, dated January 13, 2005, requesting that the Food and Drug Administration (FDA) determine whether TEQUIN (gatifloxacin) injection, 10 milligrams (mg)/milliliter (mL) (200 mg), approved under new drug application (NDA) 21-062 held by Bristol-Myers Squibb, was withdrawn from sale for reasons of safety or effectiveness.

The FDA has reviewed its records and determined that TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain TEQUIN (gatifloxacin) injection, 10 mg/mL (200 mg), in the *Discontinued Drug Product List of Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book).

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-2041.

Sincerely,

Elaine Tseng
Division of Regulatory Policy II
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

2005P-0023

LET 2