

January 13, 2005

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane
Rockville, MD 20852

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CITIZEN PETITION

Apotex Corp. submits this petition under section 505(j)(2)(c) of the Federal Food, Drug and Cosmetic Act, 21 CFR § 314.122 (a) and in accordance with the procedural requirements set forth in 21 CFR § 10.30. We request the Commissioner of the Food and Drugs to determine whether the Reference Listed Drug, TEQUIN[®] Injection 10 mg/mL (200 mg) - 20 mL Fill, the subject of NDA 21-062 held by the Bristol-Myers Squibb Company and approved Dec 17, 1999, was voluntarily discontinued from sale in the United States of America for safety or effectiveness reasons.

A. Action Requested

In the absence of substantive concerns pertaining to the safety or effectiveness of TEQUIN[®] Injection 10 mg/mL (200 mg) - 20 mL Fill, by the Bristol-Myers Squibb Company, the petition requests that the Abbreviated New Drug Application (ANDA) number 77-402 for Gatifloxacin Injection 10 mg/mL – 20 mL and 40 mL Fill submitted by Apotex Corp. on November 19, 2004 be eligible for approval upon completion of the review process, pursuant to section 505 (j) of the Food, Drug and Cosmetic Act and CFR § 314.122. Although not listed as discontinued in the Orange Book (Appendix A), the FDA, CDER Office of Generic Drugs, Regulatory Support has indicated that the Reference Listed Drug has been discontinued. A citizen petition must be filed and accepted in order for Apotex Corp. to receive final approval for their Gatifloxacin Injection 10 mg/mL – 20 mL Fill.

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B. Statement of Grounds

The Reference Listed Drug, TEQUIN[®] Injection 10 mg/mL (200 mg) - 20 mL Fill and TEQUIN[®] Injection 10 mg/mL (400 mg) - 40 mL Fill, the subject of NDA 21-062 held by the Bristol-Myers Squibb Company was approved on Dec 17, 1999. Since December 2002, Bristol-Myers Squibb Company only lists TEQUIN[®] Injection 10 mg/mL (400 mg) - 40 mL Fill, as reflected in their labeling (Appendix B). The Regulatory Support Branch of OGD has also confirmed this discontinuation of the Reference Listed Drug. A copy of the current package insert (Appendix C) for the reference listed product, TEQUIN[®] Injection (Gatifloxacin Injection) is provided.

In order for an ANDA applicant to utilize a discontinued Reference Listed Drug, a petition is required to ensure the product was not withdrawn for safety or efficacy reasons. The discontinuation of the Reference Listed Drug, TEQUIN[®] Injection 10 mg/mL (200 mg) - 20 mL Fill in our evaluation was a voluntary withdrawal, for issues other than safety and efficacy. Since Bristol-Myers Squibb Company is marketing only TEQUIN[®] Injection 10 mg/mL (400 mg) - 40 mL Fill, containing twice the amount of the same active ingredient, it is clear that the safety of the 20 mL Fill (200 mg) was not in question when the withdrawal occurred.

Efficacy also does not appear to be justified for the withdrawal. The Dosage and Administration section of TEQUIN[®]'s package insert (Appendix A) lists a 200 mg dose for the treatment of Uncomplicated Urinary Tract Infection (Cystitis). In addition, a 200 mg dose is also listed for Adult Patients with Renal Impairment. As the 200 mg is still a viable dosage regimen as listed in the prescribing information, the efficacy of this strength, in our opinion, was not in question.

Accordingly, Apotex Corp. believes that the information presented in this Citizen's Petition supports the fact that the product was not withdrawn for the reasons of safety and efficacy and requests that our Gatifloxacin Injection 10 mg/mL – 20 mL and 40 mL Fill be eligible for approval upon completion of the review process.

C. Environmental Impact

An Environmental Impact Analysis Report for the action requested is not required as cited under 21 CFR 25.31 (a).



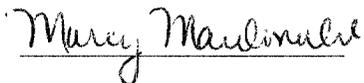
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D. Economic Impact

Information regarding economic impact will be made upon request.

E. Certification

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner, which are unfavorable to the petitioner.



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