



May 11, 2004

FILE COPY

Mr. Louis C. Cullman
Stradling Yocca Carlson and Rauth
660 Newport Center Drive, Suite 1600
Newport Beach, CA 92660-6422

Dear Mr. Cullman:

Your petition requesting authorization from Food and Drug Administration to submit an ANDA for a preservative-free Ciprofloxacin HCL (3.5 mg/mL equivalent to 3.0 mg/mL base) ophthalmic solution, unit dose containers (0.4 mL), was received by this office on 05/11/04. It was assigned docket number 2004P-0222/CP 1 and it was filed on 05/11/04. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Division of Dockets Management
Office of Management Programs
Office of Management

2004P-0222

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