



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

August 30, 2006

William A. Rakoczy
Rakoczy Molino Mazzochi Siwik, LLP
6 West Hubbard Street
Suite 500
Chicago, Illinois 60610

Dear Mr. Rakoczy:

Your petition requesting the Food and Drug Administration to deny any request to switch ketotifen fumarate ophthalmic solution, 0.025%, from prescription status to over-the-counter (OTC) status, was received by this office on 08/29/2006. It was assigned docket number 2006P-0361/CP 1 and it was filed on 08/29/2006. 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,

Gloria Ortega
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0361

ACK 1