



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

February 9, 2004

**FILE COPY**

Arent Fox Kintner Plotkin & Kahn, PLLC  
1050 Connecticut Avenue, NW  
Washington, DC 20036-5339

Dear Mr. Matelski:

Your petition requesting the Food and Drug Administration to determine that Astra Zeneca LP's Dyclone (dyclonine hydrochloride) Topical Solution 0.5% and 1.0% (NDA 9-925) was voluntarily withdrawn or withheld from sale for reasons other than safety or efficacy was received by this office on 02/04/2004. It was assigned docket number 2004P-0051/CP 1 and it was filed on 02/09/2004. 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-0051

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