DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

June 30, 2003

FILE COPY

Dr. Nicholas M. Fleischer
1220 Nineteenth Street, N.W.
Suite 300
Washington, D.C. 20036-2400

Dear Dr. Fleischer.:

Your petition requesting the Food and Drug Administration to determine whether Cataflam (diclofenac potassium) Tablets 25 mg (NDA 20-142 ), manufactured by Novarits Pharmaceuticals Corporation, have been voluntarily withdrawn or withheld from sale for safety or effectivenss reasons, was received by this office on 0627/2003. It was assigned docket number 2003P-0300/CP 1 and it was filed on 06/30/2003. 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
Dockets Management Branch

2003P-0300

ACK!