



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

FILE COPY

December 14, 2006

Derrick Mann
Caraco Pharmaceutical Laboratories, Ltd.
1150 Elijah McCoy Drive
Detroit, MI 48202

Dear Mr. Mann:

Your petition requesting the Food and Drug Administration to determine that the Reference Listed Drug, Hydrochloride Tablets USP 100 mg, the subject of ANDA 85-022, held by IVAX Pharmaceuticals Inc. was voluntarily discontinued from sale in the United States of America for reasons other than safety or effectiveness was received by this office on 12/14/2006. It was assigned docket number 2006P-0513 and it was filed on 12/14/2006. 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,

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

2006P-0513

ACK 1