DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

December 18, 2006

FILE COPY

Tania Hoffman
SICOR Pharmaceuticals, Inc.
19 Hughes
Irvine, California 92618-1902

Dear Ms. Hoffman:

Your petition requesting the Food and Drug Administration to determine whether Methotrexate Injection, USP, Preservative Free, Eq. 500 mg base/20 mL, NDA No. 11-719 held by Mayne Pharma USA has been voluntarily withdrawn or withheld from sale for safety or efficacy reasons was received by this office on 12/18/2006. It was assigned docket number 2006P-0520/CP 1 and it was filed on 12/18/2006. 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,

Jennie Butler, Director
Division of Dockets Management
Office of Management Programs
Office of Management

2006P-0520

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