ANDA 77-421

Silarx Pharmaceuticals, Inc.
Attention: Nayan Raval
Executive Vice President
19 West Street
P.O. Box 449
Spring Valley, NY 10977

Dear Sir or Madam:

This is in reference to your abbreviated new drug application (ANDA) dated November 26, 2004, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Loratadine Oral Solution USP, 5 mg/5 mL.

Reference is also made to your amendments dated Februàry 3, and February 10, 2005; August 26, February 2, February 10, April 11, and May 19, 2006.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Loratadine Syrup to be bioequivalent and, therefore, therapeutically equivalent to the referenced listed drug, Claritin Hives Relief Syrup, 1 mg/mL of Schering Plough Corporation.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Sincerely yours,

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

cc: ANDA 77-421
Division File
Field Copy
HFD-610/R. West
HFD-013
HFD-610/Orange Book Staff

Approved Electronic Labeling Located at:

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\\Cdsesub1\n77421\N_000\2006-05-19\Carton Labeling\Carton Labeling Art-Work (May 2006).pdf
\\Cdsesub1\n77421\N_000\2006-05-19\Patient Leaflet\Patient Information Leaflet Art-Work (May 2006).pdf

Endorsements:
HFD-623/G.Sun/ 6/26/06
HFD-623/D.Gill/ DSGill 6-27-06
HFD-617/L.Matheny/ LMatheny 6/27/06
HFD-613/P.Birch/
HFD-613/J.Grace/

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F/T by: EW 6/23/06

APPROVAL