

SILARX

PHARMACEUTICALS, INC.

February 23, 2005

Division of Docket Management
Food and Drug Administration
Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

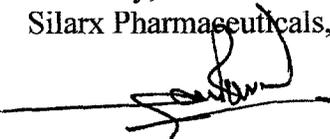
Reference: ANDA 77-421 Loratadine Syrup – Hives Relief

Dear Sir or Madam:

Herewith, we are submitting a Citizen's Petition to request Commissioner of Food and Drug Administration to allow Silarx Pharmaceuticals to reference Schering-Plough's Claritin® Hives Relief Syrup as a reference listed drug in Silarx Pharmaceutical's ANDA 77-421 for Loratadine Syrup – Hives Relief. Four copies of the Citizen's Petition are enclosed as required.

If you have any questions, please contact Mr. Ash Tankha at 856-266-5145 or me at 845-352-4020.

Sincerely,
Silarx Pharmaceuticals, Inc.



Nayan Raval
Exec. VP

Enclosures

2005P.0096

OP1

Citizen's Petition

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Department of Health and Human Services
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

The undersigned submits this petition under the Code of Federal Regulations, Title 21, Section 10.30 of the Federal Food Drug and Cosmetic Act to request the Commissioner for Food and Drug Administration to allow Silarx Pharmaceuticals to reference Schering Plough's Claritin Hives Relief Syrup as a reference listed drug product in Silarx Pharmaceutical's ANDA #77-421 for a generic equivalent of the above Schering Plough product.

A. Action Requested

Silarx Pharmaceuticals requests the Commissioner to allow Silarx to reference Schering-Plough's Claritin® Hives Relief Syrup, which is listed as a discontinued product in the Orange Book, as a Reference Listed Drug Product in Silarx Pharmaceuticals' ANDA 77-421 for Loratadine Syrup - Hives Relief.

On November 19, 2003, FDA approved Schering Plough's Claritin® Hives Relief in Tablet and Syrup dosage forms as Over-the-Counter drug products. At present, Schering-Plough markets Claritin® Hives Relief Tablets but does not market Claritin® Hives Relief Syrup which is listed as a discontinued product in the Orange Book.

B. Statement of Grounds

Loratadine has a relatively long marketing history in the U.S. and international markets. Loratadine, as an antihistamine was introduced in the international market as a prescription product in Belgium in 1988 for allergic rhinitis (AR) and chronic idiopathic urticaria (CIU). Loratadine is approved in 114 countries and as an over-the-counter (OTC) product in 33 countries. See Exhibit 1, attached.

Schering-Plough received approval of Claritin® (loratadine) in the U.S. as a prescription drug product for seasonal allergic rhinitis in April 1993 and for chronic idiopathic urticaria (CIU) in September 1995. See Exhibit 2, attached.

After a thorough review of the efficacy and safety of loratadine by the Nonprescription Drug Advisory Committee, Claritin® (Loratadine) Syrup was approved by the FDA as an over-the-counter (OTC) allergy drug product on November 27, 2002. Claritin® Hives

Relief Syrup and Tablet dosage forms were approved as OTC drug products for hives relief use by the FDA on November 19, 2003. See Exhibit 2 and 3, attached.

The strength of loratadine in both Claritin® Syrup as an allergy drug product for seasonal allergic rhinitis and Claritin® Hives Relief Syrup for hives relief use is 1 mg per 1 mL, or 5 mg per 5 mL.

At present, Schering-Plough markets Claritin® Syrup for seasonal allergic rhinitis and Claritin® Hives Relief Tablets for hives relief as OTC drug products. See Exhibit 4, attached. However, Schering-Plough has not marketed Claritin® Hives Relief Syrup, even though it was approved as an OTC product in November 2003. See Exhibit 5, attached for approved labeling. Since 2003, several generic version of Claritin® Syrup for seasonal allergic rhinitis have been approved as OTC products by the FDA.

Silarx Pharmaceuticals filed an ANDA for Loratadine Syrup for hives relief as an OTC drug product on November 26, 2004. The FDA accepted the submission under ANDA # 77-421. In ANDA #77-421, Loratadine Syrup for hives relief use references Claritin® Hives Relief Syrup as a Reference Listed Drug (RLD).

The condition of use indicated in the proposed labeling of Silarx Pharmaceutical's Loratadine Syrup in ANDA #77-412 for the strength of 5 mg per 5 mL, is identical to the RLD, Claritin® Hives Relief Syrup. See Exhibit 6, attached. Also, the active ingredient, route of administration, dosage form, and strength of Loratadine Syrup are identical to the RLD, Claritin® Hives Relief Syrup. Furthermore, the active ingredient, loratadine, in the Loratadine Syrup is of the same pharmacological or therapeutic class as in Claritin® Hives Relief Syrup. Side-by-side product comparison of Loratadine Syrup with the RLD, Claritin® Hives Relief Syrup, is provided in Exhibit 7, attached.

Side-by-side labeling comparison of Loratadine Syrup with Claritin® Hives Relief Syrup is provided in Exhibit 8, attached. The differences between the two products are highlighted and annotated in the footnote.

The patent on loratadine expired on October 21, 2004. See Exhibit 9, attached.

The current issue of the Orange Book lists Claritin® Hives Relief Syrup as a discontinued product. Claritin® Hives Relief Tablets is marketed by Schering-Plough. See Exhibit 9, attached.

Herewith, Silarx Pharmaceuticals requests the Commissioner for Food and Drug Administration to allow Silarx Pharmaceuticals to reference Schering Plough's Claritin® Hives Relief Syrup as a reference listed drug product for Silarx Pharmaceutical's ANDA 77-421 submitted for Loratadine Syrup - Hives Relief. Since Claritin® Hives Relief Syrup is not available in the market in the liquid dosage form, Silarx Pharmaceuticals' product Loratadine Syrup – Hives Relief may be the only OTC product in liquid dosage form that is available to individuals who cannot take hives relief medication in tablet or solid dosage form.

The relevant supporting documents are attached with this petition.

C. Environmental Impact

Silarx Pharmaceuticals claims for categorical exclusion under section 25.30, 25.31, 25.32, 25.33, and 25.34 of this chapter.

D. Certification

The undersigned certifies that to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Petitioner:

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Attorney for Petitioner:

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Phone: 856-266-5145

2/23/2005
Date

Loratadine Syrup Hives Relief

ANDA 77-421

List of Exhibits

- Exhibit 1 Claritin Marketing History
- Exhibit 2 FDA Review of Claritin® for OTC
- Exhibit 3
- FDA Approves OTC Claritin
 - Claritin® Syrup, Claritin® Hives Relief Syrup, and Tablet dosage forms – application and approval dates
- Exhibit 4 Claritin Hives Relief (Overview - Drugs@FDA)
- Exhibit 5 Claritin Hives Relief Syrup and Tablet Labeling
- Exhibit 6 Proposed Labeling of Silarx's Loratadine Syrup - Hives Relief
- Exhibit 7 Side-By-Side Product Comparison of Claritin Hives Relief Syrup and Silarx Loratadine Syrup – Hives Relief
- Exhibit 8 Side-By-Side Labeling Comparison of Claritin Hives Relief Syrup and Silarx Loratadine Syrup – Hives Relief
- Exhibit 9 Discontinued Product Listing from Orange Book and Expired Patent Information