Outfile

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

FEB 3 2006

0091 6 03-6 P1:52

Nayan Raval, V.P.
Silarx Pharmaceuticals, Inc.
19 West Street
Spring Valley, NY 10977

Re: Docket No. 2005P-0096/CP1

Dear Mr. Raval:

This responds to your citizen petition, dated February 23, 2005, requesting that the Food and Drug Administration (FDA) allow Silarx Pharmaceuticals, Inc. (Silarx) to reference Schering-Plough's Claritin Hives Relief syrup, which is listed as a discontinued product in the *Approved Drugs With Therapeutic Equivalence Evaluations* (the Orange Book), as a Reference Listed Drug Product in Silarx's abbreviated new drug application (ANDA) 77-421 for Loratadine Syrup – Hives Relief.

The FDA has reviewed its records and determined that CLARITIN (loratadine) Hives Relief syrup, 5 milligrams (mg) per (/) 5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. Thus, the FDA will maintain CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, in the *Discontinued Drug Product List* of the Orange Book.

Enclosed is a copy of the *Federal Register* notice that announces the FDA determination. If you require any further information, please feel free to call me at (301) 594-2041.

Sincerely,

Tawni B. Schwemer

Tawni B. Schwemer
Office of Regulatory Policy
Center for Drug Evaluation and Research

Enclosure

CC: Ash Tankha, Esq.
36 Greenleigh Drive
Sewell, NJ 08080

2005P-0096

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Summaries of Medical and Clinical Pharmacology Reviews of Pediatric Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for INVANZ (ertapenem), KEPPRA (levetiracetam), TRILEPTAL (Oxcarbazepine), and ZYVOX (linezolid). These summaries are being made available consistent with the Best Pharmaceuticals for Children Act (BPCA). For all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of the pediatric studies conducted for the supplement.

ADDRESSES: Submit written requests for single copies of the summaries to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Please specify by product name which summary or summaries you are requesting. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the summaries.

FOR FURTHER INFORMATION CONTACT: Grace Carmouze, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 1613, Silver Spring, MD 20993-0002, 301–796–2200, *carmouzeg@cder.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of summaries of medical and clinical pharmacology reviews of pediatric studies conducted for INVANZ (ertapenem), KEPPRA (levetiracetam), TRILEPTAL (Oxcarbazepine), and ZYVOX (linezolid). The summaries are being made available consistent with section 9 of the BPCA (Public Law 107–109). Enacted on January 4, 2002, the BPCA reauthorizes, with certain important changes, the pediatric exclusivity program described in section 505A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355a). Section 505A permits certain applications to obtain 6 months of marketing exclusivity if, in accordance with the requirements of the statute, the sponsor submits requested information relating to the use of the drug in the pediatric population.

One of the provisions the BPCA added to the pediatric exclusivity program pertains to the dissemination of pediatric information. Specifically, for all pediatric supplements submitted under the BPCA, the BPCA requires FDA to make available to the public a summary of the medical and clinical pharmacology reviews of pediatric studies conducted for the supplement (21 U.S.C. 355a(m)(1)). The summaries are to be made available not later than 180 days after the report on the pediatric study is submitted to FDA (21 U.S.C. 355a(m)(1)). Consistent with this provision of the BPCA, FDA has posted on the Internet at *http://www.fda.gov/cder/pediatric/index.htm* summaries of medical and clinical pharmacology reviews of pediatric studies submitted in supplements for INVANZ (ertapenem), KEPPRA (levetiracetam), TRILEPTAL (Oxcarbazepine), and ZYVOX (linezolid). Copies are also available by mail (see **ADDRESSES**).

II. Electronic Access

Persons with access to the Internet may obtain the document at *http://www.fda.gov/cder/pediatric/index.htm*.

Dated: January 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1366 Filed 2–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005P–0096]

Determination That CLARITIN (Loratadine) Hives Relief Syrup, 5 Milligrams per 5 Milliliters, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that CLARITIN (loratadine) Hives Relief syrup, 5 milligrams (mg) per (/) 5 milliliters (mL), was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for loratadine hives relief syrup, 5 mg/5mL.

FOR FURTHER INFORMATION CONTACT: Tawni B. Schwemer, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2041.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA sponsors must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is typically a version of the drug that was previously approved. Sponsors of ANDAs do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is generally known as the "Orange Book." Under FDA regulations, drugs are withdrawn from the list if the agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (§ 314.162 (21 CFR 314.162)).

Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, is the subject of approved NDA 20–641 held by Schering Corp. (now Schering-Plough Healthcare Products) (Schering). In January 2002, Schering submitted a supplemental NDA for the over-the-counter (OTC) use of CLARITIN (loratadine) syrup for the relief of itching due to hives (urticaria), to be marketed under the trade name

CLARITIN Hives Relief. FDA approved this trade name and indication for OTC use under NDA 20–641 on November 19, 2003. Schering has not marketed the 5-mg/5-mL strength of Claritin Hives Relief syrup.

In a citizen petition dated February 23, 2005 (Docket No. 2005P–0096), submitted under 21 CFR 10.30, Silarx Pharmaceuticals, Inc. (Silarx), requested that the agency determine, as described in § 314.161, whether CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness. The agency has determined that Schering's CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, approved under NDA 20–641, was not withdrawn from sale for reasons of safety or effectiveness. To date, Schering has not marketed the 5-mg/5-mL strength of its CLARITIN (loratadine) Hives Relief syrup. In previous instances (see e.g., the **Federal Register** of December 30, 2002 (67 FR 79640 at 79641) (addressing a relisting request for Diazepam Autoinjector)), the agency has determined that, for purposes of §§ 314.161 and 314.162, never marketing an approved drug product is equivalent to withdrawing the drug from sale.

FDA has reviewed its files for records concerning the withdrawal of CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL. There is no indication that the decision not to market CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, commercially is a function of safety or effectiveness concerns, and no data or information has been submitted to the docket concerning the reason for which CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL was withdrawn from sale. The identical formulation and strength is currently marketed OTC as Claritin syrup for the temporary relief of symptoms due to hay fever or other respiratory allergies: runny nose, sneezing, itching, watery eyes, and itching of the nose or throat. FDA is not aware of information that would indicate that Claritin Hives Relief syrup was withdrawn from sale for reasons of safety or effectiveness.

For the reasons outlined in this document, FDA has determined that Schering's CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the agency will continue to list CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety and effectiveness. ANDAs that refer to CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, may be approved by the agency.

Dated: January 24, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–1364 Filed 2–1–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004E–0394]

Determination of Regulatory Review Period for Purposes of Patent Extension; ALOXI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for ALOXI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent that claims that human drug product.

ADDRESSES: Submit written comments and petitions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Claudia V. Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 240–453–6681.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of Patents and Trademarks may award (for example, half the testing phase must be subtracted, as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product ALOXI (palonosetron hydrochloride). ALOXI is indicated for the following: (1) The prevention of acute nausea and vomiting associated with initial or repeat courses of moderately and highly emetogenic cancer chemotherapy, and (2) the prevention of delayed nausea and vomiting associated with initial or repeat courses of moderately and highly emetogenic cancer chemotherapy. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for ALOXI (U.S. Patent No. 5,202,333) from Roche Palo Alto, LLC, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated October 19, 2004, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of ALOXI represented the first permitted commercial marketing or use of the product. Thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for ALOXI is 3,867 days. Of this time, 3,565 days occurred during the testing phase of the regulatory review period, while 302 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355) became effective*: December 24, 1992. The applicant claims December 22, 1992, as the date the investigational new drug application (IND) became effective. However, FDA records