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that the agency determine, as described in § 314.161, whether CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, was withdrawn from sale for reasons of safety or effectiveness.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has determined that Schering's CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, approved under NDA 20–641, was not withdrawn from sale for reasons of safety or effectiveness.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been submitted to the docket concerning the reason for which CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL was withdrawn from sale.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 FDA is not aware of information that would indicate that Claritin Hives Relief syrup was withdrawn from sale for reasons of safety or effectiveness.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in this document, FDA has determined that Schering's CLARITIN (loratadine) Hives Relief syrup, 5 mg/5 mL, was not withdrawn from sale for reasons of safety or effectiveness.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

indicate that the IND effective date was December 24, 1992, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: September 27, 2002. FDA has verified the applicant's claim that the new drug application (NDA) for ALOXI (NDA 21–372) was initially submitted on September 27, 2002.

3. *The date the application was approved*: July 25, 2003. FDA has verified the applicant's claim that NDA 21–372 was approved on July 25, 2003.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,827 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments and ask for a redetermination by April 3, 2006. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 1, 2006. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Division of Dockets Management. Three copies of any mailed information are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 5, 2006.

Jane A. Axelrad,

Associate Director for Policy, Center for Drug Evaluation and Research.

[FR Doc. 06–903 Filed 2–1–06; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. 2005E–0258, 2005E–0247, and 2005E–0233]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for OMACOR and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of three applications to the Director of Patents and Trademarks, Department of Commerce, for the extension of three patents that claim 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 OMACOR (omega–3–acid ethyl esters). OMACOR is indicated as an adjunct to diet to reduce very high (= 500 milligrams per deciliter) triglyceride levels in adult patients. Subsequent to this approval, the Patent and Trademark Office received three patent term restoration applications for OMACOR (U.S. Patent Nos. 5,656,667, 5,698,594, and 5,502,077) from Pronova Biocare AS, and the Patent and Trademark Office requested FDA's assistance in determining these patents' eligibility for patent term restoration. In a letter dated July 8, 2005, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of OMACOR 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 OMACOR is 3,712 days. Of this time, 3,408 days occurred during the testing phase of the regulatory review period, while 304 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i)) became effective*: September 14, 1994. The applicant claims August 15, 1994, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND effective date was September 14, 1994, which was 30 days after FDA receipt of the IND.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the act*: January 12, 2004. FDA has verified the applicant's claim that the new drug application (NDA) for OMACOR (NDA 21–654) was initially submitted on January 12, 2004.

3. *The date the application was approved*: November 10, 2004. FDA has verified the applicant's claim that NDA