Additional Information: ACF is requesting that OMB grant a 180 day approval for this information collection under procedures for emergency processing by March 15, 2003. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275. In addition, a request may be made by sending an e-mail request to: *rsargis@acf.dhhs.gov.*

Comments and questions about the information collection described above should be directed to the following address by March 15, 2003: Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paper Reduction Project, 725 17th Street, NW., Washington, DC 20503.

Dated: February 21, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–4585 Filed 3–26–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01E–0367]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Starlix 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 Dockets Management Branch (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 Grillo, Office of Regulatory Policy (HFD–013), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3460.

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 Starlix (nateglinide). Starlix is indicated as monotherapy to lower blood glucose in patients with Type 2 diabetes (non-insulin dependent diabetes mellitus, NIDDM) whose hyperglycemia cannot be adequately controlled by diet and physical exercise and who have not been chronically treated with other anti-diabetic agents. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Starlix (U.S. Patent No. 34,878) from Novartis, 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 2, 2001, FDA advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Starlix represented the first permitted commercial marketing or use of the product. Shortly 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 Starlix is 2,147 days. Of this time, 1,775 days occurred during the testing phase of the regulatory review period, while 372 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*: March 9, 1995. The applicant claims February 7, 1995, as the date the investigational new drug application (IND) became effective. However, FDA records indicate that the IND became effective on March 9, 1995, which is 30 days after FDA's 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*: December 17, 1999. FDA has verified the applicant's claim that the new drug application (NDA) for Starlix (NDA 21–204) was initially submitted on December 17, 1999.

3. *The date the application was approved*: December 22, 2000. FDA has verified the applicant's claim that NDA 21–204 was approved on December 22, 2000.

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 1,259 days of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Dockets Management (*see* **ADDRESSES**) written comments and ask for a redetermination by April 28, 2003. 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 26, 2003. 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 Dockets Management Branch. Three copies of any information are to be submitted, except that individuals may submit a single copy. Copies 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

Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: January 13, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–4567 Filed 2–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N–0059]

Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-Based Approach; Establishment of a Public Docket

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is establishing a public docket for information relevant to the agency's current good manufacturing practice (CGMP) initiative concerning the regulation of pharmaceutical manufacturing and product quality. This action is intended to ensure that all information submitted to FDA on the CGMP initiative regarding a risk-based approach to the regulation of pharmaceutical manufacturing and product quality is available to all interested persons in a timely fashion.

ADDRESSES: The public dockets are located in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The public dockets can be accessed directly under the docket number provided and on the agency's site at *http://www.fda.gov/ohrms/dockets*.

FOR FURTHER INFORMATION CONTACT: Maureen A. Hess, Center for Drug Evaluation and Research (HFD–6), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5461.

SUPPLEMENTARY INFORMATION:

I. Background

On August 21, 2002, FDA announced that it is undertaking a significant new initiative to enhance the regulation of pharmaceutical manufacturing and product quality. The initiative entitled ''Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach,'' applies to veterinary drugs and human drugs, including biological drug products. Additional detailed information describing the scope and purpose of the initiative can be found on the Internet at www.fda.gov/bbs/topics/NEWS/2002/NEW00829.html. FDA has received recommendations on how the agency should implement various aspects of, as well as, the overall CGMP initiative and encourages further recommendations. To provide timely public access to these recommendations, FDA is establishing a public docket through which interested persons can have access to these recommendations and other information submitted to FDA. FDA expects to place submissions it receives on this initiative in the public docket.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding the CGMP initiative. Submit a single copy of electronic comments to *http://www.fda.gov/dockets/ecomments* or two hard copies of any mailed comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 21, 2003.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

[FR Doc. 03–4568 Filed 2–26–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Availability of Final Comprehensive Conservation Plan for Crescent Lake National Wildlife Refuge, Ellsworth, NE

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Pursuant to the Refuge Improvement Act of 1997, the U.S. Fish and Wildlife Service has published the Crescent Lake National Wildlife Refuge Comprehensive Conservation Plan and Summary. This Plan describes how the FWS intends to manage the Crescent Lake NWR for the next 10 to 15 years.

ADDRESSES: A copy of the Plan or Summary may be obtained by writing to U.S. Fish and Wildlife Service, Crescent Lake National Wildlife Refuge Complex, 115 Railway Street, Suite C109, Scottsbluff, NE 69363–1346; or download from *http://mountain-prairie.fws.gov/planning/*

FOR FURTHER INFORMATION CONTACT: Steve Knode, Complex Manager, U.S. Fish and Wildlife Service, Crescent Lake NWR, 115 Railway Street, Suite C109, Scottsbluff, NE 69363–1346, phone 308/635–7851; fax 308/635–7841; e-mail: *steve_knode@fws.gov*

SUPPLEMENTARY INFORMATION: The 45,849-acre Crescent Lake National Wildlife Refuge, established in 1931, is located 28 miles north of Oshkosh, Nebraska in Garden County at the southwestern end of the Nebraska Sandhills. It is administered by the U.S. Fish and Wildlife Service as part of the Crescent Lake National Wildlife Refuge Complex and is within the Central Flyway. The Complex headquarters is 100 miles to the west in the City of Scottsbluff, NE.

The initial Refuge was 36,920 acres, acquired primarily from one large ranch. Additional lands were acquired between 1932 and 1937. Most lands were acquired or exchanged under the authority of the Migratory Bird Conservation Act (45 Stat. 1222). About 2,566 acres were acquired under the Resettlement Administration (Executive Order 7027, April 30, 1935), a drought and depression relief program.

The Nebraska Sandhills were settled largely as a result of the Kincaid Act of 1904, a modification of the Homestead Act to allow settlers 640 acres in ''less productive'' areas. As a result, a homestead existed in almost every meadow. However, 640 acres was not a viable farm/ranch unit in the Sandhills, and land was soon consolidated into larger units. Today, the Sandhills are home to some of the largest ranches in the country. Because of the large acreage required to support economically viable units, Garden County is among the least densely populated areas in the continental United States. Most of the Refuge location names originated from the early homesteaders.

The availability of the Draft CCP/Environmental Assessment (EA) for 30-day public review and comment was noticed in the **Federal Register** on Wednesday, May 1, 2002, in Volume 67, Number 84, page 21711. The Draft CCP/EA identified and evaluated four management alternatives for the Crescent Lake National Wildlife Refuge as to their effectiveness in achieving the Refuge's purposes and their impact on the human environment for the next 15 years. Alternative 1—No Action Alternative which would continue the current management for the Refuge and not include extensive restoration of