

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]

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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]

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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