

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]

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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

wetland and grassland habitats; Alternative 2—historical management of refuge habitats and wildlife to replicate pre-settlement conditions; Alternative 3—the intensive management of refuge habitats and refuge program to increase outputs in certain areas; and the preferred Alternative 4—modified historical management of habitats for native birds and wild animals and to pursue a more natural historic management regime. The alternatives were assessed in the Draft CCP management plan and Environmental Assessment. Based on this assessment and comments received, the preferred Alternative 4 was selected for implementation.

The preferred alternative was selected because it best meets the purposes of the Refuge to reserve and set apart as a refuge and breeding ground for birds and wild animals. The preferred alternative will also provide for public access for wildlife-dependent recreation, and provides environmental education opportunities related to fish and wildlife resources.

Dated: October 2, 2002.

Elliott Sutta,

Acting Regional Director, Denver, Colorado.

[FR Doc. 03-4590 Filed 2-26-03; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Draft Environmental Impact Statement, Draft Environmental Impact Report, and Receipt of an Application for an Incidental Take Permit for the Western Riverside County Multiple Species Habitat Conservation Plan

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; reopening of comment period.

SUMMARY: The Fish and Wildlife Service is reopening the comment period on the draft Multiple Species Habitat Conservation Plan, draft Implementing Agreement, and Draft Environmental Impact Statement for an incidental take permit for 146 species in western Riverside County, California.

DATES: To ensure consideration, we must receive written comments on or before March 14, 2003.

ADDRESSES: Send comments to Mr. Jim Bartel, Field Supervisor, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, CA 92008. You also may submit comments by facsimile to (760) 431-9618.

FOR FURTHER INFORMATION CONTACT: Ms. Karen Evans, Assistant Field Supervisor, at the Carlsbad Fish and Wildlife Office (*see ADDRESSES*); telephone (760) 431-9440.

SUPPLEMENTARY INFORMATION: The County of Riverside (County), Riverside County Flood Control and Water Conservation District, Riverside County Transportation Commission, Riverside County Parks and Open Space District, Riverside County Waste Department, California Department of Transportation, California Department of Parks and Recreation, and 14 western Riverside County cities (Applicants) have applied to the U.S. Fish and Wildlife Service (Service) for an incidental take permit pursuant to section 10(a)(1)(B) of the Endangered Species Act of 1973, as amended (Act). The Applicants seek a permit to authorize incidental take of 146 species, including unlisted species that may become listed during the term of the permit. An incidental take permit is required to authorize take of listed species during urban and rural development in the approximately 5,095-square-kilometer (1.26-million-acre (1,967-square-mile)) Plan Area in western Riverside County. The proposed term of the permit is 75 years.

On November 15, 2002, we published "Notice of Availability of a Draft Environmental Impact Statement/Environmental Impact Report and Receipt of an Application for an Incidental Take Permit for the Western Riverside County Multiple Species Habitat Conservation Plan" (67 FR 69236). In that notice, we requested public comment on the draft Multiple Species Habitat Conservation Plan (MSHCP) and draft Implementing Agreement. We also made available for public review a Draft Environmental Impact Statement, which is the Federal portion of the Draft Environmental Impact Statement/Environmental Impact Report (EIS/EIR), to analyze the impacts of the MSHCP. The analyses provided in the Draft EIS/EIR are intended to inform the public of our proposed action, alternatives, and associated impacts; address public comments received during the scoping period for the Draft EIS/EIR; disclose the direct, indirect, and cumulative environmental effects of the proposed action and each of the alternatives; and indicate any irreversible commitment of resources that would result from implementation of the proposed action.

The comment period for the November 15, 2002, notice closed on January 14, 2003. We are now reopening the comment period for 15 days on the

draft MSHCP, draft Implementing Agreement, and Draft EIS. The County of Riverside has decided not to reopen the comment period on the Draft EIR. Comments already submitted on the Draft EIS/EIR, draft Implementing Agreement, and draft MSHCP need not be resubmitted, as they will be fully considered in the final documents.

Authority: This notice is provided pursuant to section 10(a) of the Endangered Species Act, as amended (16 U.S.C. 1531 *et seq.*), and Service regulations (40 CFR 1506.6) for implementing the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Dated: February 13, 2003.

Ken McDermond,

Deputy Manager, California/Nevada Operations Office, Sacramento, CA.

[FR Doc. 03-4591 Filed 2-24-03; 4:31 pm]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Receipt of a Permit Application (Tindall) for Incidental Take of the Houston Toad

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability.

SUMMARY: Lewis Tindall (Applicant) has applied for an incidental take permit (TE-0666141-0) pursuant to Section 10(a) of the Endangered Species Act (Act). The requested permit would authorize the incidental take of the endangered Houston toad (*Bufo houstonensis*). The proposed take would occur as a result of the construction and operation of a retail store on a 1.01-acre property on Highway 71, Bastrop County, Texas.

DATES: Written comments on the application should be received on or before April 28, 2003.

ADDRESSES: Persons wishing to review the application may obtain a copy by writing to the Regional Director, U.S. Fish and Wildlife Service, P.O. Box 1306, Room 4102, Albuquerque, New Mexico 87103. Persons wishing to review the EA/HCP may obtain a copy by contacting Clayton Napier, U.S. Fish and Wildlife Service, 10711 Burnet Road, Suite 200, Austin, Texas 78758 (512/490-0057). Documents will be available for public inspection by written request, by appointment only, during normal business hours (8:00 to 4:30) at the U.S. Fish and Wildlife Service, Austin, Texas. Written data or comments concerning the application and EA/HCP should be submitted to the