Register reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the CBER Internet site at *http://www.fda.gov/cber/guidelines.htm* or on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notifications (21 CFR part 807, subpart E, OMB control number 0910–0120) premarket approval applications (21 CFR part 814, OMB control number 0910–0231), investigational device exemptions (21 CFR part 812, OMB control number 0910–0078), quality system regulation (21 CFR part 820, OMB control number 0910–0073), and medical device reporting (21 CFR part 803, OMB control number 0910–0437). The labeling provisions addressed in this guidance have been approved by OMB under OMB control number 0910–0485.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document on or before August 27, 2007. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. Submit two paper copies of any mailed comments, 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 received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3660 Filed 7–23–07; 12:02 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D–0333]

Guidance; Emergency Use Authorization of Medical Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Emergency Use Authorization of Medical Products.'' The guidance explains FDA's policies for authorizing the use of an unapproved medical product or an unapproved use of an approved medical product during a declared emergency. This guidance finalizes the draft guidance published in the **Federal Register** of July 5, 2005 (70 FR 38689).

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, rm. 14C–26, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–827–5671. Submit written comments on the guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Charlotte Christin, Office of Counterterrorism Policy and Planning (HF–29), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4067.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry, government agencies, and FDA staff entitled ''Emergency Use Authorization of Medical Products.'' This guidance describes the agency's general recommendations and procedures for issuance of emergency use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Public Law 108–276).

Section 564 of the act provides for authorization of ''emergency use'' of a medical product, after a declaration of emergency justifying an authorization is issued by the Secretary of Health and Human Services (the Secretary) based on one of the following grounds: A determination by the Secretary of Homeland Security that there is an actual or potential ''domestic emergency;'' a determination by the Secretary of Defense that there is an actual or potential ''military emergency;'' or a determination by the Secretary that there is a public health emergency under section 319 of the Public Health Service Act that affects or has the significant potential to affect national security. The Commissioner of Food and Drugs may issue an EUA for an unapproved drug, device, or biologic, or an unapproved use of an approved drug, device, or biologic, during a declared emergency if the statutory criteria set forth in section 564 of the act are met.

On July 5, 2005, FDA published for comment in the **Federal Register** a draft of this guidance. Comments received from industry, associations, health care professionals, consumers, and staff of other Federal agencies have been taken into consideration in finalizing this guidance. Changes are based on a thorough review of all comments received. As revised, the guidance includes a more detailed discussion of the scope of preemption (where applicable) and also provides points of contact for further information on several Federal liability protection and compensation programs.

This guidance document is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). It represents the agency's current thinking on emergency use authorizations of medical products. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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 Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). These collections of information have been approved under OMB control numbers 0910–0308, 0910–0230, 0910–0471, 0910–0014, 0910–0078, and 0910–0595.

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: July 20, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–3661 Filed 7–23–07; 12:28 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Stone Lakes National Wildlife Refuge, Sacramento County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability: final comprehensive conservation plan and finding of no significant impact.

SUMMARY: The U.S. Fish and Wildlife Service (Service) announces that the Stone Lakes National Wildlife Refuge (Refuge) Final Comprehensive Conservation Plan (CCP), and Finding of No Significant Impact (FONSI) are available for distribution. The CCP prepared pursuant to the National Wildlife Refuge System Improvement Act of 1997, and in accordance with the National Environmental Policy Act of 1969, describes how the Service will manage the Refuge for the next 15 years.

DATES: The CCP and FONSI are available now. Implementation of the CCP may begin immediately.

ADDRESSES: Copies of the CCP may be obtained by writing to the U.S. Fish and Wildlife Service, Attn: David Bergendorf, CNO Refuge Planning Office, 2800 Cottage Way, W–1832, Sacramento, CA 95825. Copies of the CCP may be viewed at this address or at Stone Lakes National Wildlife Refuge, 1624 Hood-Franklin Road, Elk Grove, CA 95757. The CCP is also available for viewing and downloading online at: *http://www.fws.gov/stonelakes/ccp.htm.*

Printed copies of the CCP and FONSI are also available at the following libraries: Sacramento Central Library, 828 I Street, Sacramento, CA 95814; Arden-Dimick Library, 891 Watt Avenue, Sacramento, CA 95864; Belle Cooledge Library, 5600 South Land Park Drive, Sacramento, CA 95822; Elk Grove Library, 8962 Elk Grove Blvd., Elk Grove, CA 95624; Clarksburg Yolo County Library, 52915 Netherlands Road, Clarksburg, CA 95612; Colonial Heights Library, 4799 Stockton Blvd., Sacramento, CA 95820; Courtland Library Neighborhood Library, 170 Primasing Avenue, Courtland, CA 95615; and the Galt Branch Library (Marian O. Lawrence Library), 1000 Caroline Avenue, Galt, CA 95632.

FOR FURTHER INFORMATION CONTACT: Beatrix Treiterer, acting Project Leader, Stone Lakes National Wildlife Refuge, 1624 Hood-Franklin Road, Elk Grove, CA 95757 or David Bergendorf, Refuge Planner, 2800 Cottage Way, W–1832, Sacramento, CA 95825, phone (916) 414–6503.

SUPPLEMENTARY INFORMATION:

Background

The Refuge was established in 1994 primarily to protect and manage wintering habitat for migratory birds and to protect endangered and threatened species. The Refuge is located in the Beach-Stone Lakes Basin within the Sacramento Valley in southwestern Sacramento County; it lies south of the city of Sacramento, straddling Interstate 5 from the town of Freeport south to Lost Slough.

The Draft CCP and Environmental Assessment (EA) was available for a 30-day public review and comment period, which was announced via several methods including press releases; updates to constituents; and in the **Federal Register** (71 FR 55801, September 25, 2006). Due to requests from constituents, the review and comment period was extended for an additional 30 days. The Draft CCP/EA identified and evaluated three alternatives for managing the Refuge for the next 15 years. Alternative A was the no-action alternative, which described current Refuge management activities. Alternative B emphasized continued focus on providing wintering habitat for migratory birds and management for the benefit of special status species as well as expanding overall visitor services. Alternative C focused on providing wintering habitat for migratory birds and management for the benefit of endangered species, while placing greater emphasis on management and restoration of historic habitat conditions and expanding overall visitor services.

The Service received 25 letters, faxes and e-mails, and one phone call on the Draft CCP and EA during the review period. Many comments were also received during two public comment meetings, which were held on October 4 and 5, 2006. The comments received were incorporated into the CCP, when possible, and are responded to in an appendix to the CCP. In the FONSI, Alternative B was selected for implementation and is the basis for the CCP. The FONSI documents the decision of the Service and is based on the information and analysis contained in the EA.

Under the selected alternative, the Refuge will continue its focus of providing wintering habitat for migratory birds and management to benefit endangered species. Management programs for migratory birds and other Central Valley wildlife will be expanded and improved and public use opportunities will also be expanded. The number of Refuge units open to the public will increase from one to five. In addition, environmental education, interpretation, wildlife observation, wildlife photography, hunting, and fishing programs will be expanded.

The selected alternative best achieves the Refuge's purposes, vision, and goals; contributes to the Refuge System mission; addresses the significant issues and relevant mandates; and is consistent with principles of sound fish and wildlife management.

Dated: July 20, 2007.

Ken McDermond,

Acting Manager, California/Nevada Operations, Sacramento, California.

[FR Doc. E7–14425 Filed 7–25–07; 8:45 am]

BILLING CODE 4310–55–P