the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. 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 (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 medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA recently approved for marketing the medical device OP–1 IMPLANT. OP–1 IMPLANT is indicated for use as an alternative to the patient's own bone (autograft) in recalcitrant long bone nonunions where autograft is unfeasible and alternative treatments have failed. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for OP–1 IMPLANT (U.S. Patent No. 5,258,494) from Stryker Corp., 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 31, 2001, FDA advised the Patent and Trademark Office that this medical device had undergone a regulatory review period and that the approval of OP–1 IMPLANT 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 OP–1 IMPLANT is 3,627 days. Of this time, 3,485 days occurred during the testing phase of the regulatory review period, while 142 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date a clinical investigation involving this device was begun*: November 14, 1991. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360j(g)) for human tests to begin became effective November 14, 1991.

2. *The date the application was initially submitted with respect to the device under section 515 of the act (21 U.S.C. 360e)*: May 29, 2001. The applicant claims May 25, 2001, as the date the premarket approval application (PMA) for OP–1 IMPLANT (PMA HO10002/A01) was initially submitted. However, FDA records indicate that PMA HO10002/A01 was submitted on May 29, 2001.

3. *The date the application was approved*: October 17, 2001. FDA has verified the applicant's claim that PMA HO10002/A01 was approved on October 17, 2001.

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 1,837 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may by submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments and ask for a redetermination by June 2, 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 September 29, 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 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 Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 7, 2003.

Jane A. Axelrad,

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

[FR Doc. 03–7820 Filed 4–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03D–0111]

Draft Guidance for Federal Agencies and State and Local Governments; Potassium Iodide Shelf Life Extension; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for Federal agencies and State and local governments entitled ''Potassium Iodide Shelf Life Extension.'' This document is intended to provide guidance to Federal agencies and to State and local governments on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets. The draft guidance discusses FDA recommendations on the requisite testing for KI tablet shelf life extensions, the qualifications of laboratories suitable to conduct the tests, and issues regarding notification of holders of stockpiled KI tablets as well as end users about changes to batch shelf life once testing has been successfully conducted.

DATES: Submit written or electronic comments on the draft guidance by June 2, 2003. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance 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*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Richard Adams, Center for Drug Evaluation and Research (HFD–643), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–5849.

SUPPLEMENTARY INFORMATION:

I. Background

In November 2001, FDA provided guidance on the safe and effective use of KI tablets as an adjunct to other public health protective measures in the event that radioactive iodine is released into the environment (66 FR 64046, December 11, 2001). The guidance entitled ''Potassium Iodide as a Thyroid Blocking Agent in Radiation Emergencies'' updated FDA's 1982 recommendations for the use of KI tablets to reduce the risk of thyroid cancer in radiation emergencies involving the release of radioactive iodine. The recommendations in that guidance addressed KI dosage and the projected radiation exposure at which the drug should be used. In April 2002, FDA issued another guidance, ''Frequently Asked Questions on Potassium Iodide (KI).'' Additional information was provided for emergency pediatric dosing in ''Home Preparation Procedure for Emergency Administration of Potassium Iodide Tablets to Infants and Small Children,'' updated on July 3, 2002.

This draft guidance entitled ''Potassium Iodide Shelf Life Extension,'' is intended to provide Federal agencies and State and local governments information on testing to extend the shelf life of stockpiled potassium iodide (KI) tablets. The agency has developed this document in response to several State inquiries on this topic. This draft guidance discusses FDA recommendations on the requisite testing for such shelf life extensions, the qualifications of laboratories suitable to conduct the tests, and issues regarding notification of holders of stockpiled KI tablets as well as end users about changes to batch shelf life once testing has been successfully conducted.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on this topic. 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 applicable statues and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Two copies of any mailed comments 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. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: March 25, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–7817 Filed 4–1–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Planned Grant Award to Hawaii County's Office of the Mayor

AGENCY: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Availability of grant funds to Hawaii County's Office of the Mayor.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment (CSAT) intends to award approximately $300,000 (total costs) per year for 3 years to Hawaii County's Office of the Mayor. The first year's award will be made in fiscal year 2003 if the application is scored by the initial review group and concurred with by the CSAT National Advisory Council.

Hawaii County's Office of the Mayor has been selected to receive a single source award due to the devastating impact that crystal methamphetamine, also known as ''ice,'' abuse has had on the youth of Hawaii. The effects of this problem on children on the Island of Hawaii are profound, with some of the highest rates of drug use among youth in the State of Hawaii. According to the 2000 Hawaii Student Alcohol, Tobacco and other Drug Use Study conducted by the Department of Health, Alcohol and Drug Abuse Division, 10.6 percent of Hawaii County high school seniors answered in the affirmative to ''frequent drug use—more than 20 times in the past 30 days,'' compared to just 5.6 percent statewide. This study reports that the State of Hawaii has the highest use of ''ice'' by 12th graders in the Nation and that Hawaii County has the highest use of ''ice'' in the State. Findings further reveal that Hawaii County has one-third more 8th graders and one-third more 10th graders using ''ice'' than the rest of the State. There are currently no residential or intensive outpatient treatment services available on the Big Island and State resources are able to provide substance abuse treatment to only 1,500 youth. This funding will address the serious health and public safety threat that ''ice'' has on the Hawaii County youth by supporting the expansion of adolescent methamphetamine abuse treatment services to a full continuum of care.

Authority: The grant award will be made under the authority of section 509 of the Public Health Service Act, as amended. The Catalog of Federal Domestic Assistance number is 93.243.

FOR FURTHER INFORMATION CONTACT: Ms. Cheryl Gallagher, Project Officer, CSAT, SAMHSA, Rockwall II, 7th Floor, 5600 Fishers Lane, Rockville, MD 20857; telephone: (301) 443–7259; e-mail *cgallagh@samhsa.gov.*

Dated: March 25, 2003.

Richard Kopanda,

Executive Officer, Substance Abuse and Mental Health Services Administration.

[FR Doc. 03–7822 Filed 4–1–03; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Citizenship and Immigration Services

Agency Information Collection Activities: Proposed Collection; Comment Request

ACTION: 30-Day notice of information collection under review: Checklist for on-site review of schools; OMB–35.

The Department of Homeland Security, Bureau of Citizenship and Immigration Services (BCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously approved by OMB under emergency review proceedings on September 13, 2002 and the agency was granted temporary approval.

The BCIS intends to request an extension of this information collection. Therefore, the purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until May 2, 2003.