transurethral female urinary occlusion device and is intended for use in the management of stress urinary incontinence in adult women.

On July 25, 1996, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee, an FDA advisory committee, reviewed and recommended approval of the application. On August 16, 1996, CDRH approved the application by a letter to the applicant from the Director of the Office of Device Evaluation, CDRH.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

Opportunity for Administrative Review

Section 515(d)(3) of the act (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act, for administrative review of CDRH's decision to approve this application. A petitioner may request either a formal hearing under 21 CFR part 12 of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under 21 CFR 10.33(b). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the Federal Register. If FDA grants the petition, the notice will state the issue to be reviewed, the form of the review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before January 2, 1997, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h) (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: October 24, 1996.

Joseph A. Levitt,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 96–30649 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–01–F

Health Resources and Service Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Health Resources and Services Administration (HRSA) will publish periodic summaries of proposed projects being developed for submission to OMB under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, call the HRSA Reports Clearance Officer on (301) 443–1129.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Projects

1. Application for Certification as a Federally Qualified Health Center (FQHC)(OMB No.0915–0142)—Extension, No Change

The Federally Qualified Health Center (FQHC) Look-Alike application package (OMB No. 0915–0142) was developed to certify entities as FQHC providers under Medicaid and Medicare. FQHCs receive reasonable cost-related reimbursement under Medicaid and Medicare for a full range of primary health care services. The application for FQHC certification is divided into four components: (1) Need and Community Impact, (2) Health Services, (3) Management and Finance, and (4) Governance. Certified FQHC Look-Alikes must submit an annual recertification document with updated exhibits to retain designation as an FQHC.

In an effort to improve the procedures for certifying FQHCs, HRSA is considering revising the FQHC Look-Alike application (with parallel changes made to the recertification requirements). The revised version would update the application guidelines and exhibits to reflect current law, regulations, and practice. A revised application may also include more specific guidance on how applicants should document existing unmet need in the community.

These revisions will be developed during the next year. In the interim, a request for a two-year extension of OMB approval of the current form will be submitted.

ESTIMATES OF ANNUALIZED HOUR BURDEN

Form name	Number of respondents	Responses per respondent	Hours per response	Total burden hours
Application	40	1	120	4,800
Recertification	213	1	20	4,260
Total Burden	253	1	35.8	9,060

2. Assessment of HIV Counseling and Testing (C&T) Services for Women of Childbearing Age in Bureau of Primary Health Care (BPHC) Programs—NEW

The Bureau of Primary Health Care (BPHC), Health Resources and Services Administration (HRSA) is planning to conduct a survey-based study of its primary care programs to examine various implementation issues related to the design and delivery of HIV counseling and testing (HIV C&T) services to women of childbearing age and pregnant women. The study population will be a randomly selected 25 percent sample of the BPHC's programs, supplemented by oversample of specific programs (e.g., Health Care for the Homeless (Section 340); Ryan White Title III programs).

The mail survey instrument will be designed to explore various HIV C&T implementation issues and relevant research questions, including: (a) Extent to which HIV C&T services are available (provided directly by programs or through referrals), (b) attributes of the BPHC programs that offer HIV C&T services to women of childbearing age; (c) characteristics of HIV C&T services, provided by BPHC programs; (d) programmatic and population-specific barriers to delivery of HIV C&T services; (e) lessons and best practices for replication; (f) recommendations for technical assistance to facilitate timely, effective implementation. The resulting analysis and report will present program-based lessons and recommendations for assisting and improving capacity of various BPHC programs to design and implement HIV C&T services for women of childbearing age, and thus assist in promoting community-based HIV C&T services for women, especially pregnant women. Response burden is as follows:

Survey mechanism	Number of respondents	Responses/respondent	Hours per response	Total burden hours
Mail questionnaire	277	1	1.5	416

Send comments to Patricia Royston, HRSA Reports Clearance Officer, Room 14–36, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: November 26, 1996.

J. Henry Montes,

Associate Administrator for Policy Coordination.

[FR Doc. 96–30591 Filed 11–29–96; 8:45 am]

BILLING CODE 4160–15–U

National Institutes of Health

National Institute of Environmental Health Sciences: Opportunity for a Cooperative Research and Development Agreement (CRADA) and License for the Development of KAI1 in Gene Therapy Protocols for the Treatment of Metastatic Disease

AGENCY: National Institutes of Health, PHS, DHHS.

ACTION: Notice.

SUMMARY: The National Institutes of Health (NIH) seeks a company(ies) to pursue the development of gene therapy protocols involving the KAI1 metastasis suppressor gene. The National Institute of Environmental Health Sciences has established that KAI1 alterations occur in the development of malignant prostate cancer, and that its loss is correlated with progression to the metastatic phenotype.

DATES: Capability statements must be received by NIH on or before January 31, 1997.

ADDRESSES: Proposals and scientific questions about this opportunity may be addressed to Dr. J. Carl Barrett, NIEHS, Mail Drop C2–15, P. O. Box 12233, Research Triangle Park, NC 27709. Telephone (919) 541–2992; Fax (919) 541–7784; E-mail Barrett@NIEHS.NIH.GOV

Questions related to the CRADA process may be addressed to Ms. Lili Portilla, Senior Technology Transfer Specialist, National Heart, Lung, and Blood Institute, 31 Center Drive MSC 2490, Building 31, Room 1B30, Bethesda, MD 20892–2490; Phone: (301) 402–5579; Fax: (301) 594–3080; E-mail: portilll@gwgate.nhlbi.nih.gov

The NIEHS has applied for patents claiming this core technology. Non-exclusive and/or exclusive licenses for these patents covering core aspects of this project are available to interested parties. Licensing applications and licensing inquiries regarding this technology should be referred to Mr. Ken Hemby, Technology Licensing Specialist, NIH Office of Technology Transfer, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; Phone: (301) 496–7735 ext 265; Fax: (301) 402–0220; E-mail: HembyJ@6100M1.odnih.gov

SUPPLEMENTARY INFORMATION: The National Institute of Environmental Health Sciences has shown that the KAI1 gene can suppress metastasis of prostate cancer and is down regulated in human malignant prostate cancers. Therefore it is possible that treatment of patients who are diagnosed with prostate cancer in the early stages may be treated with the KAI1 gene, to prevent the metastasis of their tumors, in conjunction with other therapies that are used to eradicate the primary tumor. It has been shown that expression of KAI1 in normal cells is not toxic and does not affect cell growth.

The NIEHS of the NIH is seeking capability statements from interested parties in developing a CRADA to develop gene therapy vectors as well as to develop models in which to test the efficacy of the use of KAI1 in gene therapy. This project is with the Laboratory of Molecular Carcinogenesis, Cancer and Aging Group at the National Institute of Environmental Health Sciences, National Institutes of Health, Research Triangle Park, North Carolina. The goals are to use the respective strengths of both parties to achieve one or more of the following:

1. Develop suitable gene therapy vectors containing the KAI1 gene.

2. Develop a model for testing the efficacy of KAI1 vectors for the suppression of tumor metastasis *in vivo*, including gene delivery and metastases assays, and assessment of toxicity of treatment protocol.

It is anticipated that under this CRADA, the NIEHS will (1) provide cDNA of KAI1 gene for insertion into appropriate vectors and (2) work cooperatively with interested company(ies) to develop and test a model that is suitable to measure the ability of KAI1 to suppress tumor metastasis *in vivo*. The collaborator may also be expected to contribute financial support under this CRADA for supplies and personnel to support these projects.

Selection criteria for choosing the CRADA partner(s) will include, but not be limited to the following:

1. Experience in the development of gene therapy vectors.

2. Experience in delivery of pharmacological agents *in vivo*.

3. Ability to develop appropriate animal model for testing.