Dated: August 14, 2006.

Sally D. Atwater,

Executive Director, President's Committee for People with Intellectual Disabilities.

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BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0326]

Agency Information Collection Activities; Proposed Collection; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the publication of the criteria FDA intends to use to accredit third parties to conduct inspections of eligible manufacturers of class II or class III medical devices.

DATES: Submit written or electronic comments on the collection of information by October 23, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Jr., Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Inspection by Accredited Persons Program Under MDUFMA (OMB Control Number 0910–0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107–250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph ''g'' to section 704 of the Federal, Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program.

FDA has a guidance document that provides information for those interested in participating in this program. The guidance is entitled ''Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria.''

Description of Respondents: Businesses or other for profit organizations.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Information Collection:	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation	3	1	3	80	240
Total Hours					240

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Once an organization is accredited, it will not be required to reapply.

Dated: August 18, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14056 Filed 8–23–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Food Safety and Security Monitoring Project—Radiological Health; Announcement Type: Cooperative Agreements Under a Limited Competition; Funding Opportunity Number: Request for Applications: RFA–FDA–ORA–2006–4; Catalog of Federal Domestic Assistance Number: 93.448

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

I. Funding Opportunity Description

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Division of Federal-State Relations (DFSR), is announcing the availability of cooperative agreements for equipment, supplies, personnel, training, and facility upgrades to Food Emergency Response Laboratory Network (FERN) radiological laboratories of State, local, and tribal governments. The cooperative agreements are to enable the analyses of foods and food products in the event that redundancy and/or additional laboratory surge capacity is needed by FERN for analyses related to radiological terrorism or other emergency situation. These cooperative agreements are also intended to expand participation in networks to enhance Federal, State, local, and tribal governmental food safety and security efforts.

The goal of ORA's cooperative agreement program is to complement and improve State, local and Indian tribal governmental food safety and security testing programs. This will be accomplished through the provision of supplies, personnel, facility upgrades, training in current food testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, participation in method enhancement activities to extend analysis capability, and analysis of surveillance samples. In the event of a large-scale radiological terrorism event affecting foods or food products, the recipient may be required to perform selected radiological analyses of domestic and imported food samples collected and supplied to the laboratory by FDA or other Federal agencies through FDA. These samples may consist of, but are not limited to, the following: vegetables and fruits (fresh and packaged); juices (concentrate and diluted); grains and grain products; seafood and other fish products; milk and other dairy products; infant formula; baby foods; bottled water; condiments; and alcoholic beverage products.

All grant application projects that are developed at State, local, and tribal governmental levels must have national application that can enhance Federal food safety and security programs. At the discretion of the FDA, successful project formats will be made available to interested Federal, State, local and tribal government FERN laboratories.

There are two key project areas identified for this effort:

(1) The use of Gamma Spectrometry analysis for the screening and identification of gamma emitting radionuclides in foods; and

(2) The use of Beta Spectrometry analysis for the screening and identification of beta emitting radionuclides in foods.

FDA will support the projects covered by this notice under the authority of section 312 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Public Law 107–188). This program is described in the Catalog of Federal Domestic Assistance under 93.448.

1. Background

ORA is the primary inspection and analysis component of FDA/ORA has approximately 1,600 investigators, inspectors, and analysts who cover the country's approximately 95,000 FDA regulated businesses. These investigators inspect more that 15,000 facilities a year; and ORA laboratories analyze several thousand samples per year. ORA conducts special investigations, food inspection recall audits, performs consumer complaint inspections, and collects samples of regulated products. Increasingly, ORA has been called upon to expand the testing program to address the increasing threat to food safety and security through intentional radiological terrorism events. ORA developed radiological screening and analysis methodologies that are used to evaluate foods and food products in such situations. However, in the event of a large-scale emergent incident, analytical sample capacity in ORA field laboratories has a finite limit. Information from ongoing relationships with state partners indicates limited redundancy in state food testing laboratories, both in terms of analytical capabilities and analytical sample capacity. Several state food testing laboratories lack the specialized equipment to perform the analyses and/or the specific methodological expertise in the types of analyses performed for screening foods and food products involving radiological terrorism events.

Subtitle A of Title III of the Bioterrorism Act, Protection of Food Supply, section 312-Surveillance and Information Grants and Authorities, amends part B of Title III of the Public Health Service Act to authorize the Secretary of Health and Human Services (the Secretary) to award grants to States and Indian tribes to expand participation in networks to enhance Federal, State, and local food safety efforts. This may include meeting the costs of establishing and maintaining the food safety surveillance, technical, and laboratory capacity needed for such participation.

2. Program Research Goals

The goal of ORA's cooperative agreement program is to complement and improve State, local and Indian tribal food safety and security testing programs. This will be accomplished through the provision of equipment, supplies, personnel, facility upgrades, training in current food testing methodologies, participation in proficiency testing to establish additional reliable laboratory sample analysis capacity, analysis of surveillance samples, and in cooperation with FDA, participation in method enhancement activities designed to extend analytical capabilities. In the event of a large-scale radiological terrorism event affecting foods or food products, the recipient may be required to perform selected radiological analyses of domestic and imported food samples collected and supplied to the laboratory by FDA or other Federal agencies through FDA. These samples may consist of, but are not limited to, the following: vegetables and fruits (fresh and packaged); juices (concentrate and diluted); grains and grain products; seafood and other fish products; milk and other dairy products; infant formula; baby foods; bottled