

Marketing (NCHM), Centers for Disease Control and Prevention (CDC).

*Background and Brief Description*

A central component of the CDC's mission is to strengthen the nation's public health infrastructure by coordinating public health surveillance at CDC and providing domestic and international support through scientific communications and terrorism preparedness and emergency response. The Epidemic Information Exchange (Epi-X) provides CDC and its state and local partners and collaborators with a secure public health communications network intended for routine and emergent information exchange in a secure environment.

Great attention has been focused on improving secure public health communications networks for the dissemination of critical disease outbreak and/or bioterrorism-related

events, which may have multi-jurisdictional involvement and cause disease and death within a short time-frame.

The purpose of the information gathered during this notification proficiency testing exercise is to evaluate the extent to which new registrants and currently authorized users of the Epidemic Information Exchange (Epi-X) are able to utilize alert notification functionality to minimize or prevent unnecessary injury or disease-related morbidity and mortality through the use of secure communications and rapid notification systems. In this case, notification alerts would be sent to targeted public health professionals through a "barrage" of office cell phone, home telephone, and pager calls to rapidly inform key health authorities from multidisciplinary backgrounds and multiple jurisdictions of evolving and critical public health information, and

assist with the decision-making process. Presently, the necessity of this evaluation process is timely because of ongoing terrorism threats and acts perpetrated worldwide.

The survey information will be gathered through an online questionnaire format, and help evaluate user comprehension and facility solely with the targeted notification and rapid alerting functionalities of Epi-X. The questionnaire will consist of both closed- and open-ended items, and will be administered through Zoomerang, an online questionnaire program, or as a last resort, by telephone. Approximately 1,000 Epi-X users from every state of the union will be asked to volunteer input (in a 5-10 question format) about their experiences using the alert notification functionalities of the Epi-X communications system. There will be no cost to respondents, whose participation will be strictly voluntary.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Public Health Professionals .....	1,000	1	10/60	167

Dated: June 29, 2007.

**Maryam I. Daneshvar,**

*Acting Reports Clearance Officer, Centers for Disease Control and Prevention.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**Cooperative Agreement to Support the Joint Institute for Food Safety and Applied Nutrition**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2007 (FY) to the University of Maryland, College Park (UMCP) to support the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). This award will strengthen existing programs and allow expansion of JIFSAN's education, outreach and applied research programs and external partnerships that have already been established.

**DATES:** Applications are due within 30 days after the publication of the funding opportunity in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Gladys M. Bohler, Office of Acquisition and Grants Services, Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301-827-7168, or e-mail: gladys.melendez-bohler@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Funding Opportunity Description**

*Funding Opportunity Number; Notice of Intent to Renew a Cooperative Agreement; RFA-FD-07-001 CFSAN Catalog of Federal Domestic Assistance Number: 93.103*

An estimated amount of support in FY07 will be for up to \$2.0 million (direct plus indirect cost) the total amount being subject to annual budget appropriations, with an additional 4 years of support. JIFSAN is located on the University of Maryland Campus in College Park, MD. Competition is limited to UMCP because of the unique partnership between FDA and UMCP. The cooperative agreement will continue to allow for a more efficient use of research, scientific, education, and outreach resources which enhance overall public health by expanding and

improving food safety and nutrition as well as other program areas that impact on public health policy.

**II. Eligibility Information**

FDA believes UMCP is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. UMCP is in close proximity to the FDA's Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine offices and laboratories in Prince Georges County, MD. UMCP has vast resources which complement and greatly expand FDA's research, scientific, education and outreach resources. As the UMCP and FDA are both located within the greater Washington, DC area increased interactions with the USDA Beltsville Agricultural Research Center and other world class research and medical institutions are possible. UMCP is the Washington region's most comprehensive research institution, with numerous academic programs relevant to FDA's mission and the resources to support CFSAN's areas of interest, including: microbiology, chemistry, food science, animal health sciences, agriculture, public policy, risk assessment, computational science, economics, and survey methodology. UMCP serves as a primary center for

graduate study and research and provides undergraduate and graduate instruction across a broad spectrum of academic disciplines. The University extends its intellectual resources to the community through innovative projects designed to serve individuals, governments and the private sector throughout the State of Maryland, the nation, and the international community.

The University has developed core facilities to provide effective use of state-of-the-art scientific instrumentation with high acquisition, installation, and maintenance costs to conduct research at the forefront of science. An electron microscopy facility jointly supported by FDA and the University opened in 2000. CFSAN has moved its nuclear magnetic resonance (NMR) instrumentation and personnel to the University's NMR facility in the Chemistry building. These instrumentation centers complement CFSAN's resources and expertise. The University has developed <http://www.FoodRisk.org> (formerly the Risk Analysis Clearinghouse) which is the only web-based information resource specializing in food safety risk analysis, including risk assessment, risk management, and risk communication. Users include government officials from around the world seeking the latest risk assessment, or training and workshop opportunities. The Web site for FoodRisk.org contains: (1) Data and tools for researchers seeking to fill data gaps, build models, and develop expertise; (2) specialized data, peer networks, and access to modeling tools for risk assessors and project managers; and (3) the latest risk assessments, and information on workshops and training opportunities for interested individuals from around the world. The Web site for FoodRisk.org also operates the Food and Agricultural Organization/World Health Organization (FAO/WHO) Acrylamide in Food Network, the internationally sanctioned repository for information about the safety and prevention of acrylamide in food.

The University through JIFSAN has developed a broad range of international agreements with: (1) The Ministry of Science and Technology Thailand; (2) the Korea Food and Drug Administration (KFDA); (3) the Central Science Laboratory, Department for Environment Food and Rural Affairs in York, UK; and (4) the Department of Natural Resources and Environment in Victoria Australia. Additionally JIFSAN has been designated a Pan American Health Organization/World Health Organization (PAHO/WHO) Collaborating Center for Food Safety

Risk Analysis. These agreements enable UMCP and JIFSAN to: (1) Further promote international scientific, education, outreach and cooperative research activities; and (2) deepen the understanding of the scientific, economic and social issues/needs within the respective countries.

Acknowledging the importance of an interdisciplinary approach to knowledge, the University maintains organized research units outside the usual academic department structures. Through collaborative projects, FDA has access to additional University resources that include: (1) The Center for Risk Communication Research where cooperative projects related to risk communication studies have been and will continue to be developed; (2) The Center for Food Systems Security and Safety, within the College of Agriculture and Natural Resources, providing opportunities for the development of multidisciplinary food safety research using an integrated food systems approach; and (3) The Maryland NanoCenter established as a partnership among the A. James Clark School of Engineering, the College of Computer, Math, and Physical Sciences (CMPS), and the College of Chemical and Life Sciences provides access to major nano-research, equipment and informational seminars that could foster trans-disciplinary collaboration among a critical mass of researchers spanning the sciences and engineering.

As UMCP is part of the University System of Maryland (comprised of eleven universities, two research institutions and two regional higher education centers) additional education, research and outreach expertise through affiliated campuses/faculty may be accessed to build additional relationships that advance our mutual goals. Collaboration between the public and the private sectors has proven to be an efficient means for both FDA and the University to remain current with scientific and technical advances associated with FDA regulated products (i.e., foods, cosmetics and animal drugs and feed additives). The degree to which we nurture, develop and build on these collaborations directly impacts our ability to enhance public health. The information and expertise obtained through this partnership between FDA and UMCP can be leveraged by all segments of the food safety and nutrition community, as well as by public health organizations, other Federal agencies, and academic institutions in the performance of their roles.

As of October 1, 2003, applicants are required to have a DUNS number to

apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

### III. Application and Submission

FDA will accept the application for this program electronically via <http://www.grants.gov>. The applicant is encouraged to apply electronically by visiting the Web site <http://www.grants.gov> and following instructions under "Apply for Grants." The required application, SF 424 (Research & Related) (also referred to as the "SF424 (R&R)"), can be completed and submitted online. The package should be labeled "Response to RFA-FD-07 001". If you experience technical difficulties with your online submission you should contact Gladys M. Bohler by telephone 301-827-7168 or by e-mail: [gladys.melendez-bohler@fda.hhs.gov](mailto:gladys.melendez-bohler@fda.hhs.gov).

Information about submitting an application electronically can be found on the <http://www.grants.gov> Web site. In order to apply electronically, the applicant must have a DUNS number and register in the central contractor registration (CCR) database.

#### A. Dun and Bradstreet Number (DUNS)

As of October 1, 2003, applicants are required to have a DUNS number to apply for a grant or cooperative agreement from the Federal government. The DUNS number is a 9-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, call 1-866-705-5711. Be certain that you identify yourself as a Federal grant applicant when you contact Dun and Bradstreet.

#### B. Central Contractor Registration

Applicants must register with the CCR database. This database is a government-wide warehouse of commercial and financial information for all organizations conducting business with the Federal Government. The preferred method for completing a registration is through the World Wide Web at <http://www.ccr.gov>. This Web site provides a CCR handbook with detailed information on data you will need prior to beginning the online pre-registration, as well as steps to walk you through the registration process. You must have a DUNS number to begin your

registration. For foreign entities the Web site is <http://www.grants.gov/RequestaDUNS.gov>. In order to access grants.gov an applicant will be required to register with the Credential Provider. Information about this is available at <https://apply.grants.gov/OrcRegister>.

A copy of the complete RFA can also be viewed on FDA's Center for Food Safety and Applied Nutrition Web site at <http://www.cfsan.fda.gov/list.html>. (FDA has verified the Web site and its address but we are not responsible for changes subsequent to the Web site or its address after this document publishes in the **Federal Register**).

#### IV. Agency Contacts

For issues regarding the programmatic aspects of this document, contact Christine L. Hileman, Center for Food Safety and Applied Nutrition (HFS-006), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-1674, or e-mail: [christine.hileman@fda.hhs.gov](mailto:christine.hileman@fda.hhs.gov).

For issues regarding the administrative and financial management aspects of this document contact, Gladys Melendez-Bohler at 301-827-7168 or by e-mail: [gladys.melendez-bohler@fda.hhs.gov](mailto:gladys.melendez-bohler@fda.hhs.gov).

Dated: June 26, 2007.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2007N-0238]

#### Medical Devices: The Mammography Quality Standards Act of 1992 and Subsequent Mammography Quality Standards Reauthorization Act and Amendments; Inspection Fees

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the increased fees the agency will assess for inspections of mammography facilities starting October 1, 2007. The Mammography Quality Standards Act of 1992 (the MQSA) requires FDA to assess and collect fees from mammography facilities to cover the costs of annual inspections required by the MQSA. Because these costs have increased, FDA is raising the fees to ensure the program is able to meet its objective of ensuring that high quality

mammography remains available to women. This document explains which facilities are subject to payment of inspection fees, provides information on the costs included in developing inspection fees, and provides information on the inspection billing and collection processes.

**DATES:** Effective October 1, 2007, for all inspections conducted under section 354(g) of the Public Health Service Act (PHS Act) (42 U.S.C. 263b(g)). Submit written or electronic comments by October 1, 2007.

**ADDRESSES:** Submit written comments 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>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Helen J. Barr, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 240-276-3332, FAX: 240-276-3272.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

The MQSA requires all mammography facilities, other than facilities of the Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services, as meeting quality standards (section 354(b) and (d) of the PHS Act). The MQSA requires FDA to establish and operate the following: (1) A Federal certification and inspection program for mammography facilities, (2) regulations and standards for accreditation bodies, and (3) standards for equipment, personnel, quality assurance, and recordkeeping and reporting by mammography facilities (section 354(c), (e), (f), and (g) of the PHS Act). The MQSA requires annual facility inspections to determine compliance with the quality standards (section 354(g) of the PHS Act). Section 354(r) of the PHS Act requires FDA to assess and collect fees for inspections of mammography facilities, other than governmental entities as determined by FDA, to cover the costs of inspections.

An updated resource review has demonstrated that the recoverable costs of the MQSA inspection program have increased since the last notice on fees in 2003 (68 FR 5289, September 4, 2003). In addition, the annual amount of fees collected under the current fee schedule has been well below the level

authorized by Congress. FDA needs to be able to collect the full cost of mammography inspections to ensure it has the resources to ensure high quality mammography remains available to women. Accordingly, the fees have been recalculated so that the aggregate amount of fees collected will equal the aggregate recoverable costs of the inspections conducted, as mandated by the MQSA. Therefore, FDA is providing notice of the increased fees to be assessed starting on October 1, 2007, and additional information relating to those fees.

#### II. Inspections Under the Mammography Quality Standards Act of 1992

Section 354(g)(1) of the PHS Act requires FDA, States as Certifier (SAC) States, or a State or local agency acting on behalf of the FDA, to conduct an annual inspection of each mammography facility. The purpose of the annual inspection is to determine facility compliance with quality standards established under the MQSA. Inspectors who have met Federal training requirements and who are qualified by FDA will conduct inspections.

Under ordinary circumstances, inspections will be conducted during the regular business hours of the facility or at a mutually agreed time. FDA normally will provide 5 working days advance notice of each annual inspection. If a significant deficiency is identified during an inspection, FDA will provide information on necessary corrective action and, in appropriate cases, will schedule a followup inspection after the facility has had a reasonable time to correct the deficiency. FDA normally will provide 5 working days advance notice of each followup inspection. FDA may make unannounced inspections or may provide shorter notice if prompt action is necessary to protect the public health (see section 354(g)(4) of the PHS Act).

#### III. Costs Included in the Fees to Be Assessed Beginning on October 1, 2007

Section 354(r) of the PHS Act requires FDA to assess and collect fees from persons who own or lease mammography facilities, or their agents, to cover the costs of inspections conducted by FDA, SAC States, or a State or local agency acting on behalf of FDA. Section 354(r) of the PHS Act limits FDA's discretion in setting inspection fees in three ways: (1) Fees must be set so that, for a given fiscal year (FY), the aggregate amount of fees collected will equal the aggregate costs of inspections conducted; (2) a facility's