Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 7, 2004.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORATION CONTACT: JonnaLynn Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Generic Food and Drug Administration Rapid Response Surveys—(OMB Control Number 0910–0500—Extension)

Section 505 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355), requires that important safety information relating to all human prescription drug products be made available to FDA so that it can take appropriate action to protect the public health when necessary. Section 702 of the act (21 U.S.C. 372) authorizes investigational powers to FDA for enforcement of the act. Under section 519 of the act (21 U.S.C. 360i), FDA is authorized to require manufacturers to report medical device-related deaths, serious injuries, and malfunctions to FDA, to require user facilities to report device-related deaths directly to FDA and to manufacturers, and to report serious injuries to the manufacturer. Section 522 of the act (21 U.S.C. 360l) authorizes FDA to require manufacturers to conduct postmarket surveillance of medical devices. Section 705(b) of the act (21 U.S.C. 375(b)) authorizes FDA to collect and disseminate information regarding medical products or cosmetics in situations involving imminent danger to health or gross deception of the consumer. Section 903(d)(2) of the act (21 U.S.C. 393(d)(2)) authorizes the Commissioner of Food and Drugs to implement general powers (including conducting research) to carry out effectively the mission of FDA. These sections of the act enable FDA to enhance consumer protection from risks associated with medical products usage that are not foreseen or apparent during the premarket notification and review process. FDA's regulations governing application for agency approval to market a new drug (21 CFR part 314) and regulations governing biological products (21 CFR part 600) implement these statutory provisions. Currently FDA monitors medical product related postmarket adverse events via both the mandatory and voluntary MedWatch reporting systems using FDA Forms 3500 and 3500A (OMB control number 0910–0291) and the vaccine adverse event reporting system. FDA is seeking OMB clearance to collect vital information via a series of rapid response surveys. Participation in these surveys will be voluntary. This request covers rapid response surveys for community based health care professionals, general type medical facilities, specialized medical facilities (those known for cardiac surgery, obstetrics/gynecology services, pediatric services, etc.), other health care professionals, patients, consumers, and risk managers working in medical facilities. FDA will use the information gathered from these surveys to obtain quickly vital information about medical product risks and interventions to reduce risks so the agency may take appropriate public health or regulatory action including dissemination of this information as necessary and appropriate.

In the **Federal Register** of January 7, 2004 (69 FR 923), FDA published a 60–day notice requesting public comment on the information collection provisions. No comments were received.

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
200	30 (maximum)	6,000	0.5	3,000

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

FDA projects 30 emergency risk-related surveys per year with a sample of between 50 and 200 respondents per survey. FDA also projects a response time of 0.5 hours per response. These estimates are based on the maximum sample size per questionnaire that FDA can analyze in a timely manner. The annual frequency of response was determined by the maximum number of questionnaires that will be sent to any individual respondent. Some respondents may be contacted only 1 time per year, while other respondents may be contacted several times annually, depending on the human drug, biologic, or medical device under evaluation. It is estimated that, given the expected type of issues that will be addressed by the surveys, it will take 0.5 hours for a respondent to gather the requested information and fill in the answers.

Dated: April 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–10267 Filed 5–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Cooperative Agreement to Support the Illinois Institute of Technology's National Center for Food Safety and Technology; Notice of Intent to Accept and Consider a Single Source Application; Availability of Funds for Fiscal Year 2004

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN) is announcing its intent to accept and consider a single source application for

the award of a cooperative agreement to the Illinois Institute of Technology (IIT) to support the National Center for Food Safety and Technology (NCFST). FDA anticipates providing $2,750,000 (direct and indirect costs) in fiscal year 2004 in support of this project. Subject to the availability of Federal funds and successful performance, 4 additional years of support up to $5,000,000 per year (direct and indirect) will be available.

DATES: Submit applications by June 7, 2004.

ADDRESSES: Application forms are available from, and completed applications should be submitted to Maura Stephanos, Division of Contracts and Grants Management (HFA–531), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7183. If an application is hand-carried or commercially delivered, it should be addressed to 5630 Fishers Lane, rm. 2129, Rockville, MD 20857, FAX: 301–827–7101, e-mail: *mstepha1@oc.fda.gov*. Do not send the application to the Center for Scientific Review, National Institutes of Health (NIH). An application not received by FDA in time for orderly processing will be returned to the applicant without consideration. FDA can not receive an application electronically.

FOR FURTHER INFORMATION CONTACT:

Regarding the administrative and financial management aspects contact: Maura Stephanos (see **ADDRESSES**).

Regarding the programmatic aspects contact: Donald Zink, Center for Food Safety and Applied Nutrition (HFS–300), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1693, FAX: 301–436–2632, e-mail: *dzink@cfsan.fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Introduction

FDA is announcing its intention to accept and consider a single source application from IIT (RFA–FDA–CFSAN–04–1) to support the NCFST. FDA's authority to enter into grants and cooperative agreements is set out in section 301 of the Public Health Service Act (42 U.S.C. 241). FDA's research program is described in the Catalog of Federal Domestic Assistance No. 93.103. Before entering into cooperative agreements, FDA carefully considers the benefits such agreements will provide to the public. This application is not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs (45 CFR part 100). The cooperative agreement is intended to maintain and facilitate the further development of NCFST for the purpose of enhancing food safety to the benefit of the public. Specifically, NCFST is expected to maintain its collaborative research program involving FDA, academia, and the food industry; to continue to focus its research and outreach efforts on the safety of food processing and processed foods; to continue to maintain its food safety library resources; and to maintain and utilize its unique pilot plant resources to support the development and validation of new and emerging food processing technologies.

II. Background

In the **Federal Register** of May 3, 1988 (53 FR 15736), FDA published a request for applications for a cooperative agreement to establish a National Center for Food Safety and Technology, which would join the resources of government, academia, and industry in a consortium to study questions of food safety. FDA awarded the cooperative agreement to IIT in September 1988. The applications received in response to this announcement were competitively reviewed by a panel of non-FDA food scientists, and the award to IIT was approved by the National Advisory Environmental Health Science Council in September 1988.

In the **Federal Register** notices of September 10, 1991 (56 FR 46189), May 12, 1994 (59 FR 24703), and July 22, 1999 (64 FR 39512), FDA published notice of its intention to limit consideration for the award of a cooperative agreement to IIT to support the NCFST. FDA awarded the cooperative agreement to IIT on September 30, 1991, September 26, 1994, and September 27, 1999, respectively, following competitive review of the applications by a panel of non-FDA food scientists. The award was approved by the National Advisory Environmental Health Sciences Council in September 1991, September 1994, and September 1999, respectively.

Under the cooperative agreement, NCFST was established by IIT to bring together the food safety and technology expertise of academia, industry, and FDA for the purpose of enhancing the safety of the food supply in the common goal of enhancing and improving the safety of food for U.S. consumers. NCFST is structured so that representatives of participating organizations play a role in establishing policy and administrative procedures, as well as identifying long and short-term research needs. With this organizational structure, NCFST is able to build cooperative food safety programs on a foundation of knowledge about current industrial trends in food processing and packaging technologies, regulatory perspectives from public health organizations, and fundamental scientific expertise from academia. The structure and programs at NCFST positioned the center as a key component of FDA's food safety and security program. Specifically, the work at NCFST focuses on the development and evaluation of new food processing technologies and preventive technologies targeted to reduce or eliminate harmful chemical and microbial contamination of foods. Also, the center is the focal point for the agency's program on food packaging development and evaluation. The work at NCFST complements and feed into other activities at the Joint Institute for Food Safety and Applied Nutrition at the University of Maryland. NCFST is still unique in that CFSAN's Division of Food Processing and Packaging is located at the center to facilitate the kind of close relationship between academia, government and industry that the project requires. Scientists from all three sectors can work together in the labs and pilot plant of the center on projects of common interest. Finally, IIT has cultivated a base of continuing support from the food industry in the form of industry members who contribute financial support to the center and provide management direction to the center to ensure that industry needs are addressed. There is not another existing center where FDA has access to the industry relationships and research resources present at NCFST.

III. Delineation of Substantive Involvement

Substantive involvement by the awarding agency is inherent in the cooperative agreement award. Accordingly, FDA will have substantial involvement in the program activities of the project funded by the cooperative agreement. Substantive involvement includes, but is not limited to, the following:

1. FDA will appoint a project officer or co-project officers who will actively monitor the FDA-supported program under this award.

2. FDA shall have prior approval on the appointment of all key administrative and scientific personnel proposed by the grantee.

3. FDA will be directly involved in the guidance and development of the

program and of the personnel management structure for the program.

4. FDA scientists will participate, with the grantee, in determining and carrying out the methodological approaches to be used. Collaboration will also include data analysis, interpretation of findings, and, where appropriate, co-authorship of publications.

IV. Availability of Funds

It is anticipated that FDA will fund this cooperative agreement at a level approximately $2,750,000 (direct and indirect costs) for the first year. An additional 4 years of support up to approximately $5,000,000 (direct and indirect costs) each year will be available, depending upon fiscal year appropriations, and successful performance.

V. Reasons for Single Source Selection

FDA believes that there is compelling evidence that IIT is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. IIT's Moffett Campus, where NCFST is located, is a unique research facility which includes an industrial-size pilot plant and smaller pilot plants for food processing and packaging equipment, a pathogen containment pilot plant, a packaging laboratory, analytical laboratories, offices, containment facilities, classrooms, and support facilities which permit research from benchtop to industrial-scale. The industrial-size pilot plant is built to accommodate routine food processing and packaging research in a commercial atmosphere. The physical layout of the facility provides maximum versatility in the use and arrangement of equipment of both commercial and pilot size, and in the capability to simultaneously operate several different pieces of equipment without interference with each other. In addition to facilities to conduct routine processing research, there are facilities suitable for more complex research, notably a pathogen containment pilot plant research facility, funded by the State of Illinois, which has been used to study the survival of pathogens in aged cheeses. Other facilities include smaller containment facilities in which research involving use of components that may be potentially hazardous, such as pathogens in pasteurization or modified atmosphere packaging research, may be conducted.

Since 1988, IIT has provided an environment in which scientists from diverse backgrounds such as academia, government, and industry, have brought their unique perspectives to focus on contemporary issues of food safety. NCFST functions as a neutral ground where scientific exchange, about generic food safety issues, occurs freely and is channeled into the design of cooperative food safety programs. NCFST has become a center of cutting edge technologies, such as high pressure processing, pulsed electric field processing, electrical resistance processing, ultraviolet processing, and high pressure processing. Ongoing research on packaging materials is focused on providing more alternatives for use with irradiation. A workshop, with participation by representatives of government, academia, and industry, was held to discuss the use of irradiation as an intervention to prevent microbial contamination of foods and the need to alternative packaging materials for use with this technology. This led to the development of cooperative research on the safety of polymeric packaging materials for in-package irradiation. This type of research fills existing gaps in knowledge and expertise associated with improving the safety of foods at a time when concern about food contamination and resultant illnesses is high. Most recently, NCFST has gained expertise in conducting research under biosafety level 3 conditions and is in the process of renovating a facility to accommodate this type of research.

This cooperative research will provide fundamental food safety information, in the public domain, for use by all segments of the food science community in product and process development, regulatory activities, academic programs, and consumer programs. A particular use of this type of data by both industry and public health agencies is in hazard analysis critical control point (HACCP) and other types of preventive control programs. Food manufacturers will use the information in the design of HACCP programs, for use in their plants, which prevent food safety hazards before they occur and enhance the safety of the final product. Public health agencies can design investigational techniques to meet the needs of HACCP systems used in manufacturing plants.

An academic degree program (which is not part of the cooperative agreement) in food safety science has been underway for several years at IIT. The program produces graduates with a foundation in food science and technology with specialization in food safety. Graduates from this program will manage quality control, safety assurance, and HACCP programs in industry. They will design equipment and processes for use in the production and packaging of safe food products. In the public sector, regulatory and other public health organizations, these graduates will evaluate the adequacy of processing and packaging parameters to produce safe end products and they will manage regulatory and information programs enhancing the safety of the food supply and consumer knowledge about the food supply. Graduate students from IIT are gaining hands-on experience in food safety by participating in the cooperative food safety research program. Several masters of science degrees that included research conducted on cooperative projects have been granted by IIT, in disciplines such as engineering, since the inception of NCFST.

Collaboration between the public and the private sector is an efficient means for both to remain current with scientific and technical accomplishments from a food safety perspective. These collaborative programs will produce generic knowledge and expertise to be used by all segments of the food processing and packaging industry, as well as by public health organizations, regulatory agencies, and academic institutions in the performance of their roles in the food science community. The trend toward use of HACCP and other types of preventive programs in both the domestic and international food industry as a means of assuring safety of products and as a basis for harmonizing regulatory activities, is but one example of the need for and use of this food safety knowledge and expertise. Technology transfer mechanisms, which are developing out of the cooperative food safety programs, will facilitate the movement of advanced food processing and packaging technologies into the marketplace, while assuring the safety of those products.

VI. Submission Requirements

The original and two copies of the completed grant application form PHS 398 (rev. 5/01) with copies of the appendices for each of the copies, should be submitted to Maura Stephanos (see **ADDRESSES**). The outside of the mailing package should be labeled ''Response to RFA–FDA–CFSAN–04–1''. The application will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday, on or before (see **DATES** section). Information collection requirements requested on Form PHS 398 and the instructions have been submitted by the Public Health Service (PHS) to the Office of Management and Budget (OMB) and were approved and assigned OMB control number 0925–0001.

VII. Reporting Requirements

An annual financial status report (FSR) (SF–269) is required. The original and two copies of the report must be submitted to FDA's Grants Management Officer within 90 days of the budget period expiration date of the agreement. Failure to file an annual FSR in a timely fashion may be grounds for suspension or termination of the agreement.

An annual program progress report is also required. The noncompeting continuation application (PHS 2590) will be considered the annual program progress report.

A final program progress report, FSR and invention statement must be submitted within 90 days after expiration of the project period of the cooperative agreement.

VIII. Review Procedures and Evaluation Criteria

A. Review Procedures

The application submitted by IIT will first be reviewed by grants management and program staff for responsiveness. The requested budget must not exceed $2,750,000 (direct and indirect costs) for the first year. The application will be considered nonresponsive if it is not in compliance with this document. If the application is found to be nonresponsive, it will be returned to the applicant without further consideration.

The application submitted by IIT will undergo noncompetitive dual peer review. The application will be reviewed for scientific and technical merit by an ad hoc panel of experts based upon the applicable evaluation criteria. If the application is recommended for approval, it will then be presented to the National Advisory Environmental Health Sciences Council for their concurrence.

B. Review Criteria

The application will be reviewed and evaluated according to the following criteria:

1. The application clearly demonstrates an understanding of the purpose and objectives of the cooperative agreement regarding a collaborative food safety and security program.

2. The application clearly describes the steps and a proposed schedule for planning, implementing, and accomplishing the activities to be carried out under the cooperative agreement. The application presents a clear plan and schedule of steps to accomplish the goals of the cooperative agreement.

3. The application establishes the applicant's ability to perform the responsibilities under the cooperative agreement including the availability of appropriate staff and sufficient funding.

4. The application specifies the manner in which interaction with FDA will be maintained throughout the life of the project.

5. The application specifies how IIT will monitor progress of the work under the cooperative agreement and how progress will be reported to FDA.

6. The application shall include a detailed budget that shows the following items: (1) Anticipated costs that are allowable and allocable to the project; and (2) the sources of funds to meet those needs.

IX. Mechanism of Support

Support for this project will be in the form of a cooperative agreement. This agreement will be subject to all policies and requirements that govern the research grant programs of the PHS, including the provisions of 42 CFR part 52, 45 CFR part 74, and PHS grants policy statement. The regulations issued under Executive Order 12372 do not apply. The length of support will be 1 year. Cost sharing or matching is not a requirement of this program. The NIH modular grant program does not apply to this FDA program.

X. Dun and Bradstreet Number Requirement

Beginning October 1, 2003, applicants will be required to have a Dun and Bradstreet Number (DUNS) 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.

XI. Legend

Unless disclosure is required under the Freedom of Information Act as amended (5 U.S.C. 552) as determined by the freedom of information officials of the Department of Health and Human Services or by a court, data contained in the portions of this application that have been specifically identified by page number, paragraph, etc., by the applicant as containing restricted information, shall not be used or disclosed except for evaluation purposes.

Dated: April 29, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–10266 Filed 5–5–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Healthcare Integrity and Protection Data Bank: Change in Self-Query Fee

AGENCY: Office of Inspector General (OIG), HHS.

ACTION: Notice.

SUMMARY: The Department is authorized under 45 CFR part 61, the regulations implementing the Healthcare Integrity and Protection Data Bank (HIPDB), to assess a fee on all requests for information, except requests from Federal agencies. In accordance with the HIPDB regulations, we are announcing a two-dollar decrease in the fee to practitioners, providers, and suppliers who request information about themselves (self-query) from the HIPDB. The new fee to self-query the HIPDB will be $8.00. There will be no change to the $4.25 charged for each query submitted by authorized entities to access the data bank.

EFFECTIVE DATE: The fee is effective on July 1, 2004.

FOR FURTHER INFORMATION CONTACT: Joel Schaer, Office of Management and Policy, (202) 619–0089.

SUPPLEMENTARY INFORMATION:

User Fee Amount

Section 1128E(d)(2) of the Social Security Act (the Act), as added by section 221(a) of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, specifically authorizes the establishment of fees for the costs of processing requests for disclosure and for providing information from the Healthcare Integrity and Protection Data Bank (HIPDB). Final regulations at 45 CFR part 61 set forth the criteria and procedures for information to be reported to and disclosed by the HIPDB. The Act also requires that the Department recover the full costs of operating the HIPDB through such user fees. In determining any changes in the amount of the user fee, the Department employs the criteria set forth in § 61.13(b) of the HIPDB regulations.

Specifically, § 61.13(b) states that the amount of each fee will be determined based on the following criteria:

- Direct and indirect personnel costs;