

manufacturer, packer, or distributor of the dietary supplement that bears such a statement on its label or in its labeling. FDA estimates that, each year, approximately 2,200 firms will submit the information required by section 403 of the act. We estimate that a firm will require 0.75 hours to gather the information needed and prepare a communication to FDA, for a total of 1,650 hours (2,200 x 0.75). This estimate is based on the average number of notification submissions received by the agency in the preceding 2 years.

Dated: May 26, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0232]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealers Certificate

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 information collection provisions of the Interstate Shellfish Dealers Certificate.

DATES: Submit written or electronic comments on the collection of information by August 3, 2009.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. 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:

Jonna Capezzuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

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.

Interstate Shellfish Dealers Certificate (OMB Control Number 0910-0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, "Interstate Shellfish Dealer's Certificate." FDA uses this information to publish the "Interstate Certified Shellfish Shippers List," a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Submission of Interstate Shellfish Dealer's Certificate	3,038	40	57	2,280	0.10	228

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

FDA estimates that 40 respondents will submit 2,280 Interstate Shellfish Dealer's Certificates annually, for a total burden of 228 hours (2,280 submissions x 0.10 hours = 228 hours). This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: May 27, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0671]

Cooperative Agreement to Support the Illinois Institute of Technology's National Center for Food Safety and Technology (U01)

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 2009 (FY09) to the Illinois Institute of Technology (IIT) to support the National Center for Food Safety and Technology (NCFST). The estimated amount of support in FY09 will be for up to \$7 million (direct plus indirect costs), with the possibility of 4 additional years of support for up to \$28 million, subject to the availability of funds. This award will improve public health by continued support of an applied research, education, and outreach program related to the safety of food processing technologies and processed foods.

DATES: The application due date is June 28, 2009. The anticipated start date is September 2009. The opening date was May 28, 2009.

FOR FURTHER INFORMATION AND

ADDITIONAL REQUIREMENTS CONTACT: For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at <http://www.cfsan.fda.gov/list.html>.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Request for Application Number: RFA-FD-09-004
Catalog of Federal Domestic Assistance: 93.103

A. Background

FDA has supported the NCFST under five previously awarded cooperative agreements (53 FR 15736; 56 FR 46189; 59 FR 24703; 64 FR 39512; and 69 FR 25405). 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 the 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.

B. Research Objectives

The FDA recognizes that food production and processing technology is rapidly changing, that globalization of the food supply is increasing, and that the number and nature of the hazards associated with foods are rapidly evolving. FDA intends to maintain and facilitate the further development of NCFST for the purpose of enhancing food safety to benefit the public. NCFST is uniquely positioned as a key component of FDA's food protection program. Specifically, through the center's science platforms, the research at NCFST focuses on the development and validation of food processing and packaging technologies for safety and quality; investigation and development of preventive technologies targeted to reduce or eliminate harmful chemical and microbial contamination of foods; and the effects of processing on the stability and safety of bioactive ingredients added to or naturally occurring in foods. Additionally, the development of an integrated collaborative food protection research/education/outreach program 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.

C. Eligibility Information

Competition is limited to the IIT. FDA believes that continued support of NCFST at IIT is appropriate because IIT

is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. IIT's Moffet Center, 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 bench-top 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. Additionally, NCFST has a BL3 pilot plant and laboratory as well as a select agent laboratory to conduct studies with *C. botulinum* and other selected agents. NCFST researchers have access to nutritional clinical facilities on the IIT campus for validating in humans how processing may impact the availability of bioactive ingredients added to or naturally occurring in foods.

II. Award Information/Funds Available

A. Award Amount

The estimated amount of funds available for support in FY 2009 will be for up to \$7 million (direct plus indirect costs), with the possibility of 4 additional years of support for up to \$28 million, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

This award will be funded based on the quality (e.g., how well the grantee responds to the RFA (request for application) requirements) of the application received and is subject to availability of Federal funds to support the project. In addition, if a cooperative agreement is awarded, the grantee will be informed of any additional documentation that should be submitted to FDA. This cooperative agreement program requires that the applicant substantially share in the project costs if an award is made.

FDA grants policies as described in the DHHS (Department of Health and Human Services) Policy Statement, <http://www.hhs.gov/grantsnet/adminis/gpd/index.htm>, will apply to the applications submitted and awards made in response to this FOA.