occurs, and under what circumstances? What is the role of voluntary consensus standards in developing medical device patient labeling?

(2) What risks or adverse outcomes have been reported in association with the use of medical device patient labeling? What communication barriers have been encountered, and how can they be mitigated?

(3) Is there any part of the medical device patient labeling development process that presents a barrier to receiving approval or clearance from CDRH? If so, please provide examples of the specific issues, how frequently this occurs, and suggestions which constructively address these barriers.

(4) What are the best ways to foster efficient networking with patients and advocacy groups, academic and professional organizations, industry, standards organizations, and government Agencies to address medical device patient labeling needs?

B. Medical Device Patient Labeling Needs Assessment

(1) Describe the parameters that should be used in determining priority areas of development of medical device patient labeling, including both therapeutic and diagnostic devices.

(2) What are best practices for conducting a needs assessment of medical device patient labeling?

C. Advancing Development

(1) What could advance the development and use of medical device patient labeling?

(2) How should patient labeling be considered in the development stages of all medical device labeling?

(3) What resources (*e.g.,* registries, industry, or patient advocacy groups,) could be tapped to advance the development of medical device patient labeling?

(4) What are potential changes to guidances and regulations, or advances in current science that may help develop and enhance medical device patient labeling to address the needs of medical device manufacturers, device suppliers, and device users?

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17800 Filed 7–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0411]

Cooperative Agreement for Research, Education, and Outreach in Support of the Food and Drug Administration Food Safety Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for a cooperative agreement to support the FDA Food Safety Modernization Act (FSMA) implementation efforts by the Illinois Institute of Technology's (IIT) National Center for Food Safety and Technology (NCFST). The estimated amount of support in fiscal year (FY) 2015 will be for up to $5 million (direct plus indirect costs), with the possibility of 2 additional years of support for up to $7 million each year, 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 science behind and implementation of preventive controls, and on training and technical assistance.

DATES: Important dates are as follows:

1. The application due date is August 14, 2015.
2. The anticipated start date is September 1, 2015.
3. The opening date is August 1, 2015.
4. The expiration date is August 31, 2015.

ADDRESSES: Submit the electronic application to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Wanda Honeyblue, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), 5100 Paint Branch Pkwy. (HFS–002), Rm. 4D–034, College Park, MD 20740, 301–796–3500, email: *wanda.honeyblue@fda.hhs.gov;* or Martin Bernard, Division of State Acquisitions, Agreements and Grants (DSAAG) (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240–402–7564, email: *Martin.Bernard@fda.hhs.gov.*

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.grants.gov/.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–FD–15–035

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

FDA has supported the NCFST under seven previously awarded cooperative agreements (53 FR 15736, 56 FR 46189, 59 FR 24703, 64 FR 39512, 69 FR 25405, 74 FR 26408, and 79 FR 23360). NCFST was established by IIT to bring together the food safety and technology expertise of academia, industry, and FDA for the purpose of supporting research and outreach efforts related to the safety of foods based on a common goal of enhancing the safety of the food supply for U.S. consumers. NCFST has been successful in developing research programs such as those related to low-moisture foods, and outreach programs such as those related to sprout safety; these successes were achieved as a result of NCFST partnering with industry, academia, and FDA.

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, outreach, and training 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. This award will improve public health by continued support of an applied research, education, and outreach program related to the science behind and implementation of preventive controls associated with manufacturing, processing, packing, and holding of human and animal food, and on training and technical assistance.

B. Program Objectives

With an increasingly diverse domestic and global food supply, FDA continues to face complex food safety issues associated with the foods that it regulates. Some of these complex issues can be effectively addressed by further strengthening the available science-based programs established through NCFST/Institute for Food Safety and Health (IFSH). FDA also believes that innovative research and outreach programs such as those established at NCFST/IFSH can further support the development of proactive approaches to

the prevention of food safety problems before they occur. With the enactment of FSMA in 2011, the collaboration with NCFST/IFSH has become increasingly important as FDA works to fulfill its mandate to develop a modern, prevention-based food safety system. FDA regards the development and strengthening of public-private partnerships for research and outreach on preventive controls to be a key element of its FSMA implementation strategy.

This cooperative agreement will provide continued support so that NCFST/IFSH can meet the objective to support the implementation of FSMA through research, education, and outreach, with particular emphasis on identifying the science to support implementation of preventive controls associated with manufacturing, processing, packing, and holding of human and animal food, and on training and technical assistance.

C. Eligibility Information

Competition is limited to IIT as FDA believes IIT's continued support of the Food Safety Preventive Controls Alliance (FSPCA) already established at NCFST/IFSH uniquely qualifies IIT to fulfill the objectives of the proposed cooperative agreement. IIT's Moffett Center, where NCFST is located, is a unique facility that includes offices, classrooms, a distance-learning center, and support facilities, which permit appropriate research, development, and training activities. The physical layout of the facility provides maximum versatility in the use and capability to simultaneously operate several different activities related to research, development, and training to support FSMA rules. The distance learning facility located in room 216 in building 91 of the IIT Moffett Campus is equipped with state-of-the-art audio-visual equipment for conducting and broadcasting interactive training programs and workshops to the food industry, as well as for Webinar communications with IFSH stakeholders, including government, academia, and industry.

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/IFSH 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. Activities at NCFST are focused on multiple areas associated with food safety and FSMA, including but not limited to, preventive controls for human and animal foods, supplier verification, and national training.

Since 2011, IIT has served as the coordinator of the FSPCA and, since 2012, the Sprout Safety Alliance (SSA), leveraging the expertise of academia, industry, and FDA for the purpose of developing and delivering standardized curricula related to food safety and FSMA requirements. In addition to alliance training, NCFST/IFSH plans to develop the National Training and Technical Assistance Network to provide outreach and technical assistance to industry in the future. The new distance-learning training center developed at the IIT's Moffett Center can be used to partially address training and outreach needs related to FSMA. Through this facility, training can be provided on curricula currently being developed by the FSPCA for human and animal food and by the SSA for sprouts, and for training activities related to other appropriate FSMA activities such as the Foreign Supplier Verification Program.

The proposed cooperative activities will fill existing gaps in knowledge, food safety training, and expertise for outreach associated with improving the safety of foods via FSMA implementation, and will provide fundamental food safety information in the public domain for use by all segments of the food science community for industry and regulatory training activities.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition (CFSAN) at FDA intends to commit up to $5 million in FY 2015 (direct plus indirect costs) with the possibility of 2 additional years of up to $ 7 million each year. Future year amounts will depend on annual appropriations and successful performance.

B. Length of Support

The award will provide 1 year of support and include future recommended support for 2 additional years, contingent upon satisfactory performance in the achievement of project and program objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Electronic Application, Registration, and Submission

Only one electronic application will be accepted. To submit an electronic application in response to this FOA, the applicant should first review the full announcement located at *http://www.grants.gov/.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For the electronically submitted application, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit the electronic application to: *http://www.grants.gov.*

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17795 Filed 7–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2076]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Survey on the Occurrence of Foodborne Illness Risk Factors in Selected Restaurant Facility Types

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the 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 August 20, 2015.

ADDRESSES: To ensure that comments on the information collection are received,