information regarding the use of edible tissues from investigational animals. Part 511 also requires that records be established and maintained to document the distribution and use of the investigational drug to assure that its use is safe, and that the distribution is controlled to prevent potential abuse. The Agency uses these required records under its Bio-Research Monitoring Program to monitor the validity of the studies submitted to FDA to support new animal drug approval and to assure that proper use of the drug is maintained by the investigator.

Investigational new animal drugs are used primarily by drug industry firms, academic institutions, and the government. Investigators may include individuals from these entities as well as research firms and members of the medical professional. Respondents to this collection of information are the persons who use new animal drugs investigationally.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Part	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
511.1(b)(4)	206	6.01	1,238	1	1,238
511.1(b)(5)	206	.34	70	8	560
511.1(b)(6)	206	.01	2	1	2
511.1(b)(8) (ii)	206	.07	15	2	30
511.1(b)(9)	206	.07	15	8	120
Total					1,950

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
511.1(a)(3)	206	2.30	473	1	473
511.1(b)(3)	206	6.01	1238	1	1,238
511.1(b)(7)(ii)	206	6.01	1238	3.5	4,333
511.1(b)(8)(i)	206	6.01	1238	3.5	4,333
Total					10,377

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

The estimate of the time required for reporting requirements, record preparation, and maintenance for this collection of information is based on Agency communication with industry. Based on the number of sponsors subject to animal drug user fees, FDA estimates that there are 206 respondents. We use this estimate consistently throughout the table and calculate the ''No. of Responses per Respondent'' by dividing the total annual responses by number of respondents. Additional information needed to make a final calculation of the total burden hours (*i.e.,* the number of respondents, the number of recordkeepers, the number of NCIEs received, *etc.*) is derived from Agency records.

Dated: June 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–16090 Filed 6–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0010]

Cooperative Agreement To Support Shellfish Safety Assistance Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Food Safety and Applied Nutrition (CFSAN), Office of Food Safety is announcing its intent to award a single source cooperative agreement to support the Interstate Shellfish Sanitation Conference (ISSC). The purpose of this cooperative agreement is to enhance the FDA molluscan shellfish sanitation program and provide the public greater assurance of the quality and safety of these products.

DATES: Important dates are as follows:

1. The application due date is July 15, 2011.
2. The anticipated start date is September 1, 2011.
3. The opening date is June 28, 2011.
4. The expiration date is July 16, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

For Programmatic and Technical Concerns and Questions: Paul DiStefano, Center for Food Safety and Applied Nutrition (HFS–325), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1410.

For Administrative and Financial Concerns and Questions: Gladys Melendez-Bohler, Office of Acquisitions and Grants Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301–827–7175.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–11–023, 93.103.

A. Background

The CFSAN Office of Food Safety is announcing its intent to award, a single source cooperative agreement to the ISSC in the amount of $325,000 for fiscal year 2011, direct and indirect costs combined. Subject to the

availability of Federal funds and successful performance, 4 additional years of support will be available. This effort will enhance FDA's molluscan shellfish sanitation program and provide the public greater assurance of the quality and safety of these products.

Molluscan shellfish have been recognized by FDA as a significant source of seafood-borne illnesses and continue to be the subject of congressional, State, industry, and public concern. FDA has given high priority to enhance the Agency's shellfish safety program and to provide the public greater assurance of the quality and safety of these products. FDA administers the National Shellfish Sanitation Program (NSSP). Under that program the NSSP Model Ordinance serves as guidance for State shellfish sanitation programs and the issuance of State regulations and laws concerning shellfish safety. This cooperative agreement will enhance FDA efforts to help ensure that shellfish is free of harmful pathogens.

B. Research Objectives

This proposed cooperative agreement with ISSC will continue to: (1) Address the need to improve information exchange and transfer among States, Federal Agencies, industry, and consumers; (2) strengthen State activities by providing them with procedural and policy guidance, technical training, research, consumer education, and support for States to participate in ISSC biennial meetings and ISSC committee meetings; and (3) promote efforts and projects, including research, that will contribute significantly to the ability of FDA and States to identify and implement scientifically defensible food safety controls to reduce the risk of illness associated with molluscan shellfish consumption, including *Vibrio vulnificus* and *V. parahaemolyticus.* Research efforts will provide information and data that can be used to reduce assumptions and tighten modeling outputs of the *V. vulnificus* and *V. parahaemolyticus* risk assessments developed by the Food and Agriculture Organization of the World Health Organization and FDA. Substantive accomplishments of the ISSC under previous cooperative agreements include:

1. Coordination of annual shellfish safety meetings of Federal regulators, State regulators, and industry members for the purpose of developing improved science based shellfish safety controls in the NSSP Model Ordinance for implementation by State shellfish control agencies and the shellfish industry;

2. Facilitation of the incorporation and implementation of Hazard Analysis and Critical Control Point (HACCP) into the NSSP Model Ordinance;

3. Facilitation of an ISSC Unresolved Issues Process to resolve shellfish safety program discrepancies between FDA and States, ensuring continued compliance with NSSP shellfish safety controls;

4. Coordination of NSSP Model Ordinance revisions and electronic online availability;

5. Coordination with FDA on the development and oversight of a *V. parahaemolyticus* control plan;

6. Development of an educational training video concerning the risks and control of illegal shellfish harvesting;

7. Development of an education training video concerning the public health implications associated with overboard waste discharges from harvest vessels;

8. Development of accredited online training courses for medical professionals concerning *Vibrio* illness and shellfish consumption;

9. Development and maintenance of a World Wide Web site for continuous accessibility to molluscan shellfish safety information, including up-to-date information regarding outbreaks and recalls;

10. Coordination, development and oversight of a *V. vulnificus* control plan;

11. In conjunction with FDA, conduct of retail and processing plant product sampling studies to examine *Vibrios* in molluscan shellfish that have undergone a post harvest process to reduce levels of *Vibrios;* and;

12. In conjunction with FDA, conduct of a retail shellfish study to look at the occurrence of pathogens in molluscan shellfish, including norovirus, Hepatitis A virus, *Salmonella,* and *Vibrios;* and

13. In conjunction with FDA, development of a risk-based approach to evaluating State compliance with NSSP Model Ordinance requirements for controlling the safety of molluscan shellfish.

Other substantive accomplishments of the ISSC include facilitating and coordinating development of shellstock time-temperature controls for *V. vulnificus* and *V. parahaemolyticus;* funding support for *V. vulnificus* virulent strain identification research; funding support to research the effects of ice chilling on *V. vulnificus;* funding support to research the influence of water and air temperature, dissolved oxygen, and nutrients on *V. parahaemolyticus* concentrations in Pacific oysters; funding support to conduct an economic assessment of mandating post-harvest treatment of oysters; funding support to conduct a consumer acceptance study of oysters that have been post-harvest treated to reduce *Vibrio* levels to nondetect; development of a *V. vulnificus* laboratory methodology training video; and development and broadcast of a public service announcement to alert at risk consumers of the dangers associated raw shellfish consumption.

This project will (1) enhance both the effectiveness and uniformity of the national molluscan shellfish safety program by improving the flow of information between Federal and State regulatory agencies, industry, and consumers; (2) strengthen State activities by providing assistance in such areas as procedural and policy guidance, technical training, research, consumer education, and conformity with requirements of the NSSP Model Ordinance; (3) provide for research opportunities related to shellfish safety; and (4) bring to final resolution the development and implementation by States and industry of effective *Vibrio* risk control plans that are consistent with current science, epidemiology, and HACCP based food safety measures.

Substantive involvement by FDA will include:

(1) FDA will monitor the ISSC's overall conduct under this cooperative agreement.

(2) FDA will have representation on the ISSC Executive Board, Committees, and Task Forces.

(3) FDA will collaborate and work closely with the ISSC on *V. vulnificus* and *V. parahaemolyticus* risk reduction efforts. FDA will continue to monitor State activities to ensure illness/risk reduction goals of the ISSC *V. vulnificus* control plan are met and continue to monitor State activities to ensure that the ISSC *V. parahaemolyticus* control plan is fully implemented.

(4) FDA will continue to work with ISSC to develop State program evaluation criteria.

(5) FDA will analyze State shellfish program data and information and work through the ISSC to resolve any State shellfish program problems that may impact public health.

(6) FDA will conduct training courses in growing area classification, plant sanitation, and HACCP and plant standardization for participants of the ISSC, including online training modules.

(7) FDA will work with the ISSC to develop new microbiological and marine biotoxin techniques and to develop and implement early warning systems for toxic algal blooms and new

strategies for managing areas affected by toxic algal blooms.

(8) FDA will continue to work with ISSC to establish improved mechanisms for incorporating new lab methods into the NSSP.

(9) FDA will work with the ISSC to develop NSSP Model Ordinance interpretations.

(10) FDA will take any action that may be necessary to ensure compliance with this cooperative agreement including, but not limited to the pursuit of science-based HACCP controls for managing the risk of *Vibrios,* and developing patrol, growing area classification, and plant inspection criteria.

C. Eligibility Information

Competition is limited to ISSC because it has unique capacity found nowhere else. ISSC is the primary voluntary National organization of State shellfish regulatory officials that provides guidance and counsel to the States and industry on matters of sanitary control of molluscan shellfish. ISSC is the only organization that has the established formal structure, procedures, and expertise to direct all components (public health, environmental, resource management, and enforcement) of an effective National shellfish safety program, and has operated satisfactorily in this capacity since 1993. This effort will enhance FDA's molluscan shellfish safety program and provide the public greater assurance of the quality and safety of shellfish products.

II. Award Information/Funds Available

A. Award Amount

The annual allocation to the ISSC under this cooperative agreement, including support in the amount of $75,000.00 from the National Marine Fisheries Services will be $325,000.00.

Subject to the availability of Federal funds and successful performance, 4 additional years of support will be available. CFSAN intends to fund 1 year of award to begin in September 1, 2011. Subject to annual appropriations and successful performance, 4 additional years of noncompetitive award will be available.

B. Length of Support

September 1, 2011, to August 31, 2016.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to the funding opportunity announcement (FOA), applicants should first review the full announcement located at *http://www.fda.gov/Food/NewsEvents/default.htm.* (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**.) Persons interested in applying for a grant may obtain an application at *http://grants2.nih.gov/grants/funding/phs398/phs398.html.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet Data Universal Numbering System (DUNS) Number
- Step 2: Register With Central Contractor Registration
- Step 3: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 3, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.*

After you have followed these steps, submit paper applications to: Gladys Melendez-Bohler, Office of Acquisition and Grants Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 1078, Rockville, MD 20857, 301–827–7175, *e-mail: gladys.bohler@fda.hhs.gov.*

Dated: June 22, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2011–16119 Filed 6–27–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0010]

Cooperative Agreement With the World Health Organization Department of Food Safety and Zoonoses in Support of Strategies That Address Food Safety Problems That Align Domestically and Globally (U01)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of a sole source cooperative agreement with the World Health Organization (WHO). The goal of the Food and Drug Administration, Office of the Commissioner and the Office of International Programs, Center for Food Safety and Nutrition, and the Center for Veterinary Medicine is to contribute to the knowledge base of the current state of food safety globally, including challenges, risks and emerging trends, through an integrated information system based on WHO's existing network efforts.

DATES: Important dates are as follows

1. The application due date is July 20, 2011.

2. The anticipated start date is September, 2011.

3. The opening date is the date the notice is published in the **Federal Register**.

4. The expiration date is July 21, 2011.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT: *For programmatic questions and concerns contact:* Katherine Bond, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8318; e-mail: *Katherine.bond@fda.hhs.gov.*

For financial and administrative questions and concerns contact: Gladys M. Bohler, Office of Acquistion and Grant Services, Food and Drug Administration, 5630 Fishers Lane, rm. 1078 (HFA 500), Rockville, MD 20857, 301–827–7175; e-mail: *gladys.bohler@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.fda.gov/InternationalPrograms/CapacityBuilding/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–11–021,
93.103: 93.103.

A. Background

WHO has responsibility for the provision of technical cooperation to its 193 Member States (national governments) in the area of food safety and zoonotic diseases. Among the focus areas are: Surveillance for food borne disease; identification of food contamination; management of mechanisms for information sharing; and systems for emergency response, including outbreak investigations and governments' food product recalls which may potentially have a global impact or cross national boundaries, and which may fall within the requirements of the International Health Regulations. WHO's technical support complements a paradigm shift that is emerging around the globe; a shift from a focus on food safety interventions at