FDA's burden estimate is based on prior experience with Internet panel experiments similar to the study proposed here. Sixty panel members will take part in a pretest of the study, estimated to last 30 minutes (0.5 hours), for a total of 30 hours. Approximately 10,000 respondents will complete a screener to determine eligibility for participation in the study, estimated to take 1 minute (0.0167 hours), for a total of 167 hours. Three thousand one hundred and fifty respondents will complete the full study, estimated to last 30 minutes (0.5 hours), for a total of 1,575 hours. The total estimated burden is 1,772 hours.

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10659 Filed 5–2–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0009]

Cooperative Agreement To Support the Joint Institute for Food Safety and Applied Nutrition, JIFSAN (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 the Joint Institute for Food Safety and Applied Nutrition (JIFSAN). FDA believes that University of Maryland, College Park (UMCP)–JIFSAN is a sound investment to protect and promote public health. FDA faces an increasing number of critical and complex food safety and public health issues associated with the products that FDA regulates. These complex issues can be addressed most efficiently by expanding the scientific base through the development of collaborative partnerships. FDA believes that partnering with UMCP–JIFSAN will enhance FDA's ability to address safety and other public health issues related to foods, cosmetics, and animal health and continue to stimulate the integration of applied research, education, and outreach programs.

DATES: Important dates are as follows:

1. The application due date is June 1, 2012.

2. The anticipated start date is August 1, 2012.

3. The opening date is May 3, 2012.

4. The expiration date is June 2, 2012.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Elizabeth M. Calvey, Center for Food Safety and Applied Nutrition (HFS–560), Food and Drug Administration, CPK1, Rm. 4A007 (HFS–006), 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1981, *elizabeth.calvey@fda.hhs.gov.*

Gladys Melendez, Office of Acquisition & Grants Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rm. 1078, Rockville, MD 20857, 301–827–7175, *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/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–12–016.

Catalog of Federal Domestic Assistance Number: 93.103.

A. Background

FDA is announcing its intention to receive and consider a single source application for the award of a cooperative agreement in fiscal year 2012 (FY12) to UMCP to support JIFSAN.

FDA believes that the UMCP–JIFSAN collaboration is a sound investment. The last 15 years of FDA's partnership with UMCP–JIFSAN have been successful in developing multiple programs to support public health policy. The goal of JIFSAN is to advance sound strategies that improve public health, nutrition, and food/feed safety through three broad program areas: research, education, and outreach.

With an increasingly diverse domestic and global food supply, FDA continues to face complex food safety issues associated with products that it regulates (i.e., conventional foods; food ingredients; dietary supplements; cosmetics; animal feed, feed additives, and animal drugs). FDA believes that some of these complex issues can be effectively addressed by further strengthening the available science-based programs established through JIFSAN. FDA also believes that innovative capacity-building partnerships with various sectors of stakeholders in conjunction with JIFSAN's research and training programs can further support the development of proactive approaches to the prevention of problems before they occur. A proposal is being solicited for meeting this need as well as FDA's strategic goals to protect and promote public health.

B. Research Objectives

This cooperative agreement will provide continued support so that UMCP–JIFSAN can meet the following objectives:

- Establish multi-institutional, multidisciplinary applied research projects to address complex food/feed safety and public health issues associated with products that FDA regulates. Applied research includes not only traditional laboratory and field research, but also epidemiological, educational, social and behavioral science.
- Continue the development of mechanisms for the exchange of technical information and scientific concepts between FDA and other sectors of the international and domestic community, through workshops, short courses and symposia, and online resources that focus on existing and emerging complex food/feed safety and public health issues.
- Continue the development and refinement of programs based on the application of the principles of risk analysis to address food/feed defense and safety issues.
- Continue the design and improvement of domestic and international collaborations, which foster greater implementation of effective food safety practices.
- Continue developing innovative education and outreach programs that will provide opportunities to leverage resources among various sectors of stakeholders to address complex safety issues associated with an increasingly diverse global food supply.

C. Eligibility Information

Competition is limited to UMCP–JIFSAN because UMCP–JIFSAN is uniquely qualified to fulfill the objectives of the proposed cooperative agreement. The administrative structure and policies of UMCP–JIFSAN offer the flexibility needed to create and operate strategic alliances involving multiple partners. They also allow effective utilization of resources to plan and run multidisciplinary and multi-institutional research programs and internationally-recognized food safety training and risk analysis programs.

UMCP and FDA, through their collaboration in JIFSAN, developed FoodRisk.org, which is an extensive Web-based information resource addressing many aspects of food safety risk analysis, as well as providing tools

and resources for food-borne infectious disease epidemiology and surveillance; developed a risk analysis professional development training program taught through several different modalities (*e.g.,* face-to-face and online); developed international food safety education and outreach programs that foster implementation of effective food safety practices (i.e., Good Agricultural Practices, Good Aquaculture Practices, and Commercially Sterile Packaged Foods); and, recently, established the first-of-its-kind full-time international food safety laboratory training facility at College Park, MD, to train domestic and foreign government officials, third party laboratory scientists, and food producers on fit-for-purpose analytical procedures that would meet global food safety standards.

Since its inception, JIFSAN has funded over 60 research projects as well as provided over 250 internships to undergraduate students to work with FDA scientists. JIFSAN food safety research topics are diverse and include the development of methods for detecting food pathogens; risk assessment studies on nutrients; food packaging materials; dietary supplements; microbial dose-responses; and risk communication. JIFSAN's unique structure permits it to reach beyond the UMCP campus and support research at other universities.

Moreover, UMCP–JIFSAN provides an environment in which scientific and regulatory experts from various sectors can pool their resources and ideas and promote more efficient development and dissemination of science-based information that can support public policy.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition (CFSAN) at FDA intends to fund one award up to $2.2 million for FY 2012, with the possibility of 4 additional years of support, subject to the availability of funds. Future year amounts will depend on annual appropriations and successful performance.

B. Length of Support

The award will provide 1 year of support, with the possibility of 4 additional years of support, contingent upon satisfactory performance in the achievement of project and program reporting objectives during the preceding year and the availability of Federal fiscal year appropriations.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at *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/FORMS.HTM.* For all paper application submissions, the following steps are required:

- Step 1: Obtain a Dun and Bradstreet (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:

Applications must be prepared using the PHS 398 research grant application forms and instructions for preparing a research grant application. Submit one signed, typewritten original of the application, including the checklist, and five signed photocopies as follows:

Submit one original to: Gladys Melendez, Division of Acquisition and Grant Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 1078, Rockville, MD 20857, 240–731–3905, *gladys.bohler@fda.hhs.gov.*

Submit the five signed photocopies to: Kevin W. Robinson, Center for Food Safety and Applied Nutrition (HFS–650), Food and Drug Administration, CPK1, Rm. 4C035, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2118, *kevin.robinson@fda.hhs.gov.*

Dated: April 27, 2012.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–10648 Filed 5–2–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–E–0156]

Determination of Regulatory Review Period for Purposes of Patent Extension; HALAVEN

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for HALAVEN and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions along with three copies and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6284, Silver Spring, MD 20993–0002, 301–796–3602.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Public Law 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product.