Grantee organization	City	State	Supplement award amount
Children's Hospital Los Angeles	Los Angeles	CA	$52,538.00
Cicatelli Associates Inc	New York	NY	130,506.00
Demoiselle 2 Femme	Chicago	IL	34,981.00
Education Development Center, Inc	Newton	MA	51,181.00
Lighthouse Outreach	Hampton	VA	50,000.00
OhioHealth	Columbus	OH	9,660.00
Oklahoma Institute for Child Advocacy	Oklahoma City	OK	108,009.00
The Village for Families & Children, Inc	Hartford	CT	60,000.00

DATES: The period of support under these supplements is September 30, 2012, through September 29, 2013.

FOR FURTHER INFORMATION CONTACT: Marc Clark, Program Director, Adolescent Pregnancy Prevention Program, Division of Adolescent Development and Support, Family and Youth Services Bureau, 1250 Maryland Avenue SW., Suite 800, Washington, DC 20024. *Telephone:* 202–205–8496; *Email: marc.clark@acf.hh.gov.*

SUPPLEMENTARY INFORMATION: The award of eight single source expansion supplement grants to PREIS grantees is required because of the necessary expansion of the original scope of approved activities. In reviewing grantees' aggressive program and evaluation plans, combined with recruitment efforts to date, FYSB has determined that that these eight grantees would be required to increase the number of program participants and/or increase data collection efforts. Increased funding will help the grantees' programs increase recruitment and retention strategies for program participants that will allow grantees to obtain the minimal statistical power required to report significant outcome data. Outcome data will determine the effectiveness of the implemented pregnancy prevention models used in the program. Thus, the increased number of program participants supports the evaluation requirements outlined in the FOA and the Affordable Care Act.

Additionally, grantees are required to report on performance measures that were specifically defined by FYSB. The data collection will require additional grantee staff time and other resources to compile and report on performance indicators. Performance indicators are based upon the performance measures established by the Department of Health and Human Services (HHS) to include: (a) The number of youth served and hours of service delivery; (b) fidelity to the program model or adaptation of the program model for the target population; (c) community partnerships and competence in working with the target population; and (d) reported gains in knowledge and intentions, and changes in self-reported behaviors of participants.

Award amounts for the eight single source expansion supplement grants total $496,875 and will support activities from September 30, 2012, through September 29, 2013.

Statutory Authority: Section 2953 of the Patient Protection and Affordable Care Act of 2010, Public. Law 111–148, added Section 513 to Title V of the Social Security Act, codified at 42 U.S.C. 713, authorizing the Personal Responsibility Education Program.

Bryan Samuels,

Commissioner, Administration on Children, Youth and Families.

[FR Doc. 2013–14741 Filed 6–19–13; 8:45 am]

BILLING CODE 4184–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement To Support the Western Center for Food Safety

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 Western Center for Food Safety (WCFS). FDA regards the continued support of WCFS as crucial to receiving invaluable insight into the food safety issues that it is directed to address through various provisions of the FDA Food Safety Modernization Act (FSMA). FDA concludes this partnership will enhance FDA's efforts to address the particularly complex issues surrounding the safety of agricultural production. Partnering with WCFS provides FDA with the opportunity to stimulate collaborations so that resources can be leveraged to maximize food safety research, education, and outreach efforts aimed at WCFS and FDA stakeholders particularly those within the agricultural community. A key outcome of this effort is to enhance FDA's implementation of the prevention oriented activities outlined in FSMA.

DATES: Important dates are as follows:

1. The application due date is July 15, 2013.
2. The anticipated start date is September, 2013.
3. The opening date is June 20, 2013.
4. The expiration date is July 16, 2013.

ADDRESSES: Submit the paper application to: Gladys Melendez, Grants Management (HFA–500), 5630 Fishers Lane, Rockville, MD 20857, and a copy to Kevin W. Robinson, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2118. For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Samir K. Assar, Center for Food Safety and Applied Nutrition, Food and Drug Administration, CPK1 Rm. 3A001, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1636; or Gladys Melendez, Grants Management Officer/Specialist, Office of Acquisition and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2032, Rockville, MD 20857, 301–827–7175.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–023.

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 2013 (FY13) to the University of California-Davis, Davis, CA, to support WCFS.

The partnership between WCFS and FDA over the past 5 years has been very productive in supporting FDA's public health mission by conducting studies that address knowledge gaps surrounding the safe production of agricultural foods and education/outreach activities that provide the agricultural sector with information about food safety best practices. With the enactment of FSMA in 2011, the partnership has become increasingly important as FDA works to fulfill its mandate to develop a prevention-based modern food safety system. FSMA directs the Agency to develop and implement risk and science-based enforceable standards and enhance partnerships with its food safety stakeholders. The Agency's research strategy is focused on building the scientific foundation it needs to support the development and implementation of science-based standards. The strategy involves identifying and prioritizing its research needs based on its policymaking and implementation activities. WCFS has played a critical role in conducting studies that were used to inform policy, including regulations that are being developed under FSMA, and will continue to do so as the Agency further implements FSMA activities.

FDA regards the development and strengthening of public-private partnerships to be a key element of its FSMA implementation strategy, which involves providing education and outreach to private industry about its food safety standards in order to build industry capacity to comply with these standards prior to conducting enforcement activities. The Agency has a limited history with the agricultural community and seeks to use the strong relationships that academia has with this sector to facilitate education and outreach activities. The demonstrated ability of WCFS to successfully leverage resources through existing partnerships will continue to maximize the ability to achieve research, education, and outreach objectives domestically and internationally with available funds. The Agency is developing a technical assistance network that will be critical in providing technical assistance to the farming community in adopting and complying with components of FSMA. WCFS is optimally situated to be a key player in this network to deliver quality technical assistance to a broad range of food safety stakeholders in the agricultural community.

B. Research Objectives

This cooperative agreement will provide continued support so that WCFS can meet the following research objectives:

- Continue to conduct multidisciplinary applied laboratory, field, and educational research regarding the safety of agriculture production to generate practical solutions that can be implemented by the agricultural community and consequently, enhance food safety and food defense for FDA-regulated products.
- Continue to develop and maintain communication with various stakeholders, domestic and international, involved in food production and food safety in order to identify food safety knowledge gaps and opportunities to leverage resources.
- Continue to enhance technical assistance outreach and educational efforts through various channels, including seminars, presentations, serving on technical advisory boards and committees, and outreach through agriculture extension appointments.
- Continue to engage in multi-institutional collaborations to ensure that FDA has the most current scientific thinking on best agricultural practices across varying agro-ecological landscapes.
- Continue to assist the Agency in implementing food safety standards under FSMA.

C. Eligibility Information

The University of California-Davis (UC Davis), WCFS

Competition is limited to WCFS because FDA has determined that WCFS is uniquely qualified to fulfill the objectives outlined in the proposed cooperative agreement. The program has demonstrated the adaptability necessary to address FDA's evolving high-priority public health issues. This adaptability allows WCFS to successfully leverage resources across a variety of organizations including the U.S. Department of Agriculture—National Institute of Food and Agriculture, Center for Produce Safety, numerous industry boards, and also with universities across the country. This has led to the expansion of the program and has also increased their visibility as a food safety resource thus propagating additional collaborations. In addition, the WCFS locations at the UC Davis main campus and experimental stations provide invaluable access to one of the leading food production and food safety research institutions in the country with prominent researchers and access to agricultural producers, along with other public and private stakeholders. This established UC Davis network allows WCFS to offer technical assistance that will aid in the protection of public health by increasing the adoption and understanding of guidance and policy.

WCFS has conducted research on diverse agriculture production issues of importance to FDA including common routes of contamination on a farm, environmental contamination, and agricultural practices and possesses the ability to further expand their research into other production areas. The location of WCFS affords FDA the opportunity to obtain data from meaningful, field-based trials in an important food-producing area of the country. WCFS access to field sites for experimental trials is instrumental to FDA receiving the most current scientifically validated information that relates to actual agricultural conditions. WCFS has established research collaborations with research institutions throughout the United States including Florida, Arizona, Georgia, Ohio, and Hawaii to study the agro-ecological differences that may impact food safety in the agricultural sector. WCFS has also made available research tools that can be utilized by all research institutions that could facilitate industry compliance with preventive control standards. Information gleaned from this research has been made publicly available and has been useful to domestic and international stakeholders and often translates into proactive, science-based preventive controls. FDA has utilized this information when developing policy aimed at fulfilling its public health mission. Industry boards and grower groups have also incorporated WCFS generated information into their national and regional food safety guidance documents.

WCFS has also effectively provided extensive technical outreach and education through participation on high profile advisory boards/panels covering diverse agricultural topics including but not limited to good agricultural practices, tree nuts, veterinary science, and specialty crops that span the United States. Additionally, WCFS regularly outreaches to the agricultural community through conferences and meetings to provide information about best practices. Finally, WCFS and FDA have also provided opportunities for postgraduates to be trained and mentored by WCFS and FDA scientists in areas of field, laboratory, and educational research.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition at FDA intends to fund one award up to $2 million for FY13, with the possibility of four 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 four 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://grants.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 System for Award Management (SAM)
- 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 the Grants Management Officer/Specialist listed above.

Dated: June 14, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013–14673 Filed 6–19–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–D–0369]

Draft and Revised Draft Guidances for Industry Describing Product-Specific Bioequivalence Recommendations; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of additional draft and revised draft product-specific bioequivalence (BE) recommendations. The recommendations provide product-specific guidance on the design of BE studies to support abbreviated new drug applications (ANDAs). In the **Federal Register** of June 11, 2010, FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site. The BE recommendations identified in this notice were developed using the process described in that guidance.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on these draft and revised draft guidances before it begins work on the final versions of the guidances, submit either electronic or written comments on the draft and revised draft product-specific BE recommendations listed in this notice by August 19, 2013.

ADDRESSES: Submit written requests for single copies of the individual BE guidances to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance recommendations.

Submit electronic comments on the draft product-specific BE recommendations to *http://www.regulations.gov.* Submit 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: Kris André, Center for Drug Evaluation and Research (HFD–600), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9326.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of June 11, 2010 (75 FR 33311), FDA announced the availability of a guidance for industry entitled ''Bioequivalence Recommendations for Specific Products,'' which explained the process that would be used to make product-specific BE recommendations available to the public on FDA's Web site at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm.* As described in that guidance, FDA adopted this process as a means to develop and disseminate product-specific BE recommendations and provide a meaningful opportunity for the public to consider and comment on those recommendations. Under that process, draft recommendations are posted on FDA's Web site and announced periodically in the **Federal Register**. The public is encouraged to submit comments on those recommendations within 60 days of their announcement in the **Federal Register**. FDA considers any comments received and either publishes final recommendations or publishes revised draft recommendations for comment. Recommendations were last announced in the **Federal Register** of December 17, 2012 (77 FR 74669). This notice announces draft product-specific recommendations, either new or revised, that are being posted on FDA's Web site concurrently with publication of this notice.

II. Drug Products for Which New Draft Product-Specific BE Recommendations Are Available

FDA is announcing new draft product-specific BE recommendations for drug products containing the following active ingredients:

A
Apixaban
Artemether; Lumefantrine
Asenapine maleate
B
Balsalazide disodium
C
Cycloserine
Cyclosporine
E
Eltrombopag olamine
F
Fluoxetine
H
Hydrochlorothiazide; Triamterene
M
Medroxyprogesterone (multiple reference listed drugs)
Methyltestosterone