DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0812]

Electronic Study Data Submission; Data Standard Support; Availability of the Center for Drug Evaluation and Research Data Standards Program Documents

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) of the Food and Drug Administration (FDA) is announcing the availability of the CDER Data Standards Strategy (version 1.0) and the CDER Data Standards Strategy—Action Plan (version 1.0). This action is being taken to ensure that all interested stakeholders are aware that the data standards program documents are available and is intended to increase awareness of CDER's data standards plans, ongoing projects, and avenues of communication. Comments may be submitted to the email address listed below.

FOR FURTHER INFORMATION CONTACT: Office of Strategic Programs, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1100, Silver Spring, MD 20993, 301–796–3800; email: *CDERDataStandards@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

On December 5, 2012, the CDER Data Standards Strategy (version 1.0) was released. Its purpose is to reinforce FDA's ongoing commitment to the development, implementation, and maintenance of a comprehensive data standards program to facilitate the efficient and effective review of regulatory submissions so that safe and effective products can get to market sooner. It is aligned with the objectives of FDA's Strategic Plan and the performance goals of the Prescription Drug User Fee Act V Reauthorization as captured in the FDA Safety and Innovation Act. The CDER Data Standards Strategy supersedes version 1.1 of the CDER Data Standards Plan, which was issued in December 2010.

The first release of the companion document to the Data Standards Strategy, the CDER Data Standards Strategy—Action Plan, was issued on March 20, 2013. The Action Plan provides internal and external stakeholders with an overview and progress of current relevant data standards initiatives. The plan will be updated quarterly to indicate progress of current projects as well as initiation of new projects.

These documents are available from the CDER Data Standards Program Web site at: *http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm249979.htm.*

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0010]

Cooperative Agreement to Support the World Trade Organization's Standards and Trade Development Facility

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 2013 (FY 2013) to the World Trade Organization's (WTO) Standards and Trade Development Facility (STDF).

DATES: Important dates are as follows:

1. The application due date is August 1, 2013.
2. The anticipated start date is September 2013.
3. The expiration date is August 2, 2013.

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

FOR FURTHER INFORMATION CONTACT: *Scientific/Programmatic Contact:* Julie Moss, Center for Food Safety and Applied Nutrition (HFS–550), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2031, email: *julie.moss@fda.hhs.gov.*

Grants Management Contact: Kimberly Pendleton Chew, Office of Acquisitions and Grant Services (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2105, Rockville, MD 20857, 301–827–9363, email: *kimberly.pendleton@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 *www.fda.gov/food/newsevents/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–036

93.103

A. Background

The STDF is a unique global partnership established by the Food and Agriculture Organization, World Organization for Animal Health, World Bank, World Health Organization (WHO) and the WTO. The STDF supports developing countries in building their capacity to implement international sanitary and phytosanitary (SPS) standards, guidelines, and recommendations as a means to improve their human, animal, and plant health status and ability to gain or maintain access to markets. In achieving its aims, the STDF acts as both a coordinating and a financing mechanism.

The STDF is a widely established knowledge platform for information exchange, sharing experiences and the identification and dissemination of good practice on SPS-related technical cooperation. Since 2004, over 60 projects and 52 project preparation grants have assisted developing countries to overcome SPS constraints, and gain and maintain market access. Over 50% have benefited least developed and other low-income countries.

The STDF utilizes a key decision-support tool, Multi-Criteria Decision Analysis (MCDA), to help establish SPS priorities and ensure resources are used as efficiently as possible. The use of the MCDA tool is unique within the STDF and is a highly-valued attribute; the MCDA tool facilitates an open and transparent discussion among public and private stakeholders about capacity-building needs and resources. The STDF is committed to the Paris Principles on Aid Effectiveness and to achieving the Millennium Development Goals.

With an increasingly diverse and complex global food supply, FDA's interest is to strengthen food safety systems globally to prevent food safety

problems rather than merely reacting to problems after they occur. FDA recognizes that it cannot do this alone. By leveraging with other WTO member countries and partnering with the STDF, FDA can broaden the reach of food safety capacity building efforts.

This cooperative agreement will allow FDA to deepen its international food safety capacity building partnerships, provide a wider scope of impact than exists currently and leverage resources with other countries.

B. Research Objectives

The purpose of this cooperative agreement is to:

1. Contribute to the knowledge base and development of food safety systems globally due to the increasingly diverse and complex food supply;
2. Enhance and broaden FDA's ability to address global food safety and public health issues associated with food;
3. Provide opportunities to leverage additional resources among WTO member countries;
4. Support FDA's Food Safety Modernization Act (FSMA) and its International Food Safety Capacity Building Plan, which emphasizes the concept of preventing food safety-related problems before they occur and the importance of establishing strong relationships and mutual support among all stakeholders, including multilateral organizations, to improve worldwide food safety.

C. Eligibility Information

Competition is limited to the STDF hosted by the WTO. The STDF is a global partnership with a well-established, trusted presence and is uniquely qualified to further the global food safety capacity building objectives of this cooperative agreement. STDF's mandate is to: (1) Increase awareness, mobilize resources, strengthen collaboration, identify and disseminate good practice; and (2) provide support and funding for the development and implementation of projects that promote compliance with international SPS requirements.

An independent external evaluation of the STDF in 2008 concluded that the STDF ''carries out an important role that no other single body would be able to accomplish.'' (Source: STDF Newsletter, Vol. 2, Issue 1, February 2009, accessible at: *www.standardsfacility.org*) As such, the STDF is uniquely equipped to fulfill the objectives of this cooperative agreement due to its diverse access to WTO members in both developed and developing countries and its ability to coordinate capacity building programs at a national, regional, and global level. Engaging the STDF through this cooperative agreement will provide FDA with ample opportunities to leverage additional resources among WTO member countries.

Overall, the objectives of the STDF are directly in line with the objectives of this cooperative agreement. This ability to advance the objectives of this cooperative agreement through member country engagement and leveraging is a requisite for success.

II. Award Information/Funds Available

A. Award Amount

The Center for Food Safety and Applied Nutrition intends to fund one award up to $750,000 total costs (direct plus indirect costs) for FY 2013. 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 4 additional years, 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. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic 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**.) For all electronically submitted applications, 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 electronic applications to: *http://www.grants.gov.*

Dated: July 10, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0814]

Draft Guidance for Industry on Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Pediatric Study Plans: Content of and Process for Submitting Initial Pediatric Study Plans and Amended Pediatric Study Plans.'' This draft guidance is intended to provide information to industry on how to submit initial and amended pediatric study plans (PSPs) as required under the Federal Food, Drug, and Cosmetic Act (FD&C Act) as amended by the Food and Drug Administration Safety and Innovation Act (FDASIA).

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 comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by September 13, 2013.

ADDRESSES: Submit written requests for single copies of the draft guidance 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, or Office of Communication, Outreach, and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section