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.

[FR Doc. 2013–16861 Filed 7–12–13; 8:45 am]

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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