



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0010]

Regulatory Systems Strengthening

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 Office of International Programs. The goal of the Cooperative Agreement is to strengthen global regulatory capacity through activities that may include: Development of global norms and standards for product regulation; generation and analysis of evidence of regulatory systems performance; and provision of technical support to national regulatory systems strengthening efforts.

DATES: Important dates are as follows:

1. The application due date is August 9, 2013.
2. The anticipated start date is September 10, 2013.
3. The opening date is July 10, 2013.
4. The expiration date is August 10, 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: Charles Preston, Office of Science Policy Analysis/Office of International Programs, HFG-1, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Silver Spring, MD 20993, 301-796-0654,

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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-13-024

93.103

A. Background

The World Health Organization (WHO) has responsibility for helping to ensure access to essential medical products of assured safety, quality, and efficacy within its 193 Member States. It does so in three primary areas: (1) Setting global norms and standards; (2) articulating evidence-based policy options, including those relating to regulatory systems performance; and (3) providing technical support to national regulatory authorities and governments. These activities help to strengthen national regulatory systems. In this era of globalization, products can be imported from anywhere in the world within increasingly complex supply chains. As national and global health programs work to scale up access to medicines and health products, strong national regulatory systems are more important than ever before.

What are the necessary constituents of an effective medical products regulatory system? This is an important question, and one which the U.S. Institute of Medicine recently addressed, identifying some core elements of a successful regulatory system. These include sound

government; good manufacturing, clinical, and laboratory practices; staff development and professionalization; monitoring and evaluation of product quality using laboratories; inspection and surveillance of products throughout the supply chain; risk assessment, analysis, and management; and emergency response. WHO helps to strengthen medical products regulatory systems through activities that include disseminating global quality norms and standards; facilitating the exchange of regulatory information; assessing regulatory authorities; providing training; distributing scientific materials and information on aspects of regulation from regional and global perspectives; expanding the global monitoring and surveillance system for falsified and substandard products; supporting national pharmacovigilance programs; and building capacity as a component of WHO's prequalification programs.

Another important area of work on regulatory systems strengthening is through a new Member State Mechanism (MSMech) on Substandard, Spurious, Falsified, Falsely-labeled, and Counterfeit (SSFFC) medical products, which was established as part of a resolution at the 65th World Health Assembly in May 2012. The MSMech is designed to address SSFFC issues and advance medical product safety and quality through the strengthening of national regulatory capacities. The first meeting of the MSMech occurred in Buenos Aires, Argentina, in November 2012, and the representatives agreed to form a global steering committee with representation from the WHO regions to support implementation of the workplan; the creation and management of selected work groups to address specific work areas; and the development of data-driven approaches to SSFFC issues. Participants also stressed the need for initiatives to educate consumers on the threats of SSFFC, for methodologies and instruments to obtain more accurate information about the nature and magnitude of the SSFFC problem, and for guidelines on how to better respond to the detection of SSFFC medical products.

FDA has been actively engaged with WHO on a number of these fronts. FDA experts participate in WHO drug and vaccine safety advisory committees, which develop important international norms and standards for the regulation of medical products. In addition, FDA has implemented a number of Cooperative Agreements with WHO on medical product safety and quality in recent years. In 2010, the Office of International Programs (OIP)/FDA set up a Cooperative Agreement with WHO to develop a global monitoring platform for SSFFC medical products. A steering group of experts from relevant FDA Centers provides guidance, direction, and advice regarding this cooperative effort. The overarching priority is the exchange of information about and expertise on matters relating to SSFFC so that data can be collected and contribute to the formulation of policies and programs that combat the problem. The system allows participating countries to report SSFFC information using a simple, electronic rapid alert form. Once the information has been submitted, WHO can take the appropriate first-response measures to circulate such information to governments, WHO regional offices, and other stakeholders as necessary. Analyses, threat assessments, thematic reporting, and bulletins based on the reported data may also be completed and shared.

B. Research Objectives

The Cooperative Agreement announced in this FOA represents the further expansion of well-established collaborations between WHO and OIP/FDA in support of data-driven and science-based public health strategies and approaches. These collaborations align well with FDA domestic and global goals, as outlined in its 2011 Pathway Report to Global Product Safety and Quality, including addressing medical product safety and quality problems. Relevant strategies include: (1) Developing global norms and standards; (2) generating and analyzing evidence on regulatory systems performance; and (3) providing technical support to national regulatory

systems strengthening efforts. This Cooperative Agreement is expected to support the following types of collaboration:

- Developing global norms and standards
 - Enabling the sharing of scientific findings and data through expert meetings and technical consultations;
 - Assisting Member States in the implementation and subsequent evaluation of internationally recognized standards and guidelines, e.g. WHO guidelines and standards and those emerging from standards development venues such as the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH);
 - Utilizing WHO's convening power to engage with relevant stakeholders on science-based norms and standards;
- Generating and analyzing evidence of regulatory systems performance
 - Contributing to the knowledge base of the current state of medical product regulation globally, including challenges, risks, and emerging trends;
 - Enabling and/or further strengthening the development of data/information systems as sources of inputs for evidence-based regulatory decisions and actions and enhanced knowledge management systems, coalitions, and networks;
- Providing technical support to national regulatory systems strengthening efforts
 - Enabling the strengthening of regulatory systems at the national and international levels in such critical domains as good manufacturing, clinical, and laboratory practices; developing curricula that supports regulatory professionalization; monitoring and evaluating product quality; laboratory capacity; inspection and

surveillance of products throughout the supply chain; pharmacovigilance systems building and analyses; risk assessment, analysis, and management; and making the business case for investments in regulatory systems.

C. Eligibility Information

This is a Single Source Cooperative Agreement.

II. Award Information/Funds Available

A. Award Amount

An award of up to \$1,500,000 for this cooperative agreement will be available the first year (fiscal year (FY) 2013) based on available appropriations. Funding for subsequent years for this 5-year award will be contingent on the availability of appropriations and successful performance in the award not to exceed \$1,500,000 per year.

B. Length of Support

The initial period of performance is 1 year. Contingent upon successful performance, additional awards may be available in FYs 2014, 2015, 2016, and 2017.

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 <http://www.fda.gov/InternationalPrograms/CapacityBuilding/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: Obtain 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: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2013-15101 Filed 06/24/2013 at 8:45 am; Publication Date: 06/25/2013]