DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0012]

Fostering Cooperation and Strengthening Medical Product Regulatory Systems in the Americas

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Office of International Programs (OIP) is announcing the availability of grant funds for the support of a single source cooperative agreement to the Pan American Health Organization (PAHO) for fostering cooperation and strengthening medical product regulatory systems in the Americas. The goal of the cooperative agreement is to build upon existing cooperation between OIP/FDA and PAHO to foster regulatory collaboration and strengthen regulatory capacity throughout the Americas.

DATES: Important dates are as follows:

1. The application due date is August 1, 2014.

2. The anticipated start date is October 1, 2014.

3. The expiration date is August 2, 2014.

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 M. Preston, Office of Strategy, Partnerships and Analytics, Office of International Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3309, Silver Spring, MD 20993, 301–796–0654; or Kimberly Pendleton-Chew, Food and Drug Administration, Division of Acquisitions and Grants (HFA 500), 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, 240–402–7610.

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–13–039

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A. Background

PAHO is the Regional Office for the Americas of the World Health Organization (WHO). 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 and regional regulatory authorities and governments. These activities help to strengthen regulatory systems which, in this era of globalization, where the supply chain of medicines has become a global network, and as national, regional, and global health programs work to scale up access to medicines and health products, strong regulatory systems, are imperative.

The necessary constituents of a medical products regulatory system have been defined by PAHO and WHO. They include regulatory frameworks, marketing authorization, import/export control and postmarket surveillance, licensing of manufacturers, inspections, laboratories, pharmacovigilance, clinical trials, and vaccine lot release. Specifically, PAHO helps to strengthen medical products regulatory systems through activities that include disseminating quality norms and standards, facilitating the exchange of regulatory information, evaluating regulatory authorities, providing training and technical assistance, distributing scientific materials and information on aspects of regulation, strengthening regional monitoring and surveillance for falsified and substandard products (including supporting national pharmacovigilance programs), and building capacity as a component of WHO's prequalification programs.

In recent years, OIP/FDA has been actively engaged with PAHO on a number of areas related to regulatory systems strengthening. OIP/FDA and PAHO are currently involved in a 4-year cooperative agreement which began in September 2010 that promotes medical product regulatory system strengthening in the Americas. The centerpiece of the agreement is the development of the Regional Platform for Access and Innovation of Health Technologies (PRAIS), an electronic platform for regulatory exchange. The site was launched by PAHO in 2012 and the cooperative agreement is managed by OIP, with additional strategic and technical guidance provided by a steering group of FDA Center subject matter experts. PRAIS includes features such as communities of practice, where regulators can share information and engage in real-time dialogue around regulatory issues, and an ''observatory'', where information on the basic structures and functions of participating regulatory authorities is housed.

PAHO envisions PRAIS to be a cornerstone of its regulatory system strengthening activities in the Americas. Beyond the immediate functionalities, PRAIS is also being used to prioritize and coordinate activities related to the Pan American Network for Drug Regulatory Harmonization. In addition, PRAIS is being used to develop regional models for regulatory systems; for example, data from the observatory have been used in research to assess strengths and weaknesses of regulatory systems in the Caribbean towards a regional system. Another initiative related to PRAIS is a secure platform for sharing non-public information, called PRAISsec, and FDA has been engaged in its governance and assessing agency needs and requirements. At this time, the platform is not yet built and no non-public information has been shared. A next phase of development for PRAIS may include global scale-up, which will enhance the platform's utility to other parts of the world that are in critical need of regulatory information exchange and capacity building tools.

OIP/FDA entered a similar cooperative agreement on regulatory systems strengthening with WHO in fiscal year (FY) 2014. Activities include work that WHO is undertaking at the global level, including advancement of a member state mechanism on substandard, spurious, falsified, falsely-labeled, and counterfeit medical products (SSFFC), enhancement of another FDA-supported cooperative agreement to develop a global monitoring system for SSFFC medical products, and specific work to improve regulation of active pharmaceutical ingredients among regulators in WHO's member states.

B. Research Objectives

The cooperative agreement announced in this FOA represents the further expansion of well-established collaborations between OIP/FDA and PAHO in support of data-driven and science-based public health strategies and approaches. The objective is to build upon existing cooperation to foster regulatory collaboration and

strengthen regulatory capacity throughout the Americas in ways that provide benefit and contribution to the FDA regulatory and public health mission. This partnership aligns with FDA's domestic and global goals of addressing medical product safety and quality challenges.

This cooperative agreement will support collaboration and investigation in the following areas:

1. Developing and Applying Regional/Global Norms and Standards

- Enable the sharing of scientific findings and data through expert meetings and technical consultations;
- assist 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);
- utilize PAHO's convening power to engage with relevant stakeholders on science-based norms and standards; and
- facilitate the alignment and convergence of standards between PAHO, other regions, and/or global bodies.

2. Researching Regulatory Systems Performance

- Contribute to the knowledge base of the current state of medical product regulation globally, including challenges, risks, and emerging trends, and making the business case for investments in regulatory systems; and
- enable and/or further strengthen 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.

3. Providing Technical Support to Regulatory Systems Strengthening Efforts and Expand Awareness of the Role of Regulatory Systems in the Broader Global Health Development Framework

- Enable the strengthening of regulatory systems at the regional and global levels in such critical domains as: Regulatory frameworks; marketing authorization; import/export control and postmarket surveillance; inspections; laboratories; pharmacovigilance; clinical trials and vaccine lot release; staff development and training, including the professionalization of the regulatory workforce; monitoring and evaluation of product quality; inspection and surveillance of products throughout the supply chain; and risk assessment, analysis, and management; and
- contribute strategies to expand the knowledge and awareness of the essential role of regulatory systems within the broader global health and development frameworks, including ways that can leverage existing initiatives, investments and partnerships or catalyze new ones.

C. Eligibility Information

This is a single source cooperative agreement. PAHO is eligible to apply for this award. PAHO is the Regional Office for the Americas of WHO. 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 and regional regulatory authorities and governments. In recent years, OIP/FDA has been actively engaged with PAHO on a number of areas related to regulatory systems strengthening. OIP/FDA and PAHO are currently involved in a 4-year cooperative agreement which began in September 2010 that promotes medical product regulatory system strengthening in the Americas.

II. Award Information/Funds Available

A. Award Amount

This award is contingent upon FDA appropriations and meritorious application. FDA/OIP can fund one award in the amount up to $2 million for FY 2015 based on available appropriations.

B. Length of Support

The total project period may not exceed 5 years. Funding in future years will be contingent on the availability of appropriations and successful performance in the award not to exceed $2 million per year.

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 *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: 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 2, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–N–2014–0865]

Patient-Focused Drug Development for Idiopathic Pulmonary Fibrosis; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for idiopathic pulmonary fibrosis. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of idiopathic pulmonary fibrosis on daily life as well as patient views on treatment approaches for idiopathic pulmonary fibrosis.

DATES: The public meeting will be held on September 26, 2014, from 1 p.m. to 5 p.m. Registration to attend the meeting