need for AMR surveillance with a forward-look toward sustainable solutions through global collaboration and evidence-based approaches.

C. Eligibility Information

The following organizations/institutions are eligible to apply: The World Health Organization

II. Award Information/Funds Available

A. Award Amount

FDA anticipates providing one award of $847,500 (total costs including indirect costs) in fiscal year (FY) 2010 in support of this project. Subject to the availability of funds and successful performance, 2 additional years of support up to $565,000 per year will be available.

B. Length of Support

The support will be 1 year with the possibility of an additional 2 years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a non-competing continuation application and available Federal FY appropriations.

Dated: September 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24903 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0495]

Cooperative Agreement With the Pan American Health Organization for the Development of an Information Hub for Medical Products and Related Regulatory Processes and Systems in the Americas Region

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application to award a cooperative agreement to the Pan American Health Organization (PAHO) for the development of an information hub in the areas of medical products and related regulatory processes and systems (e.g., including drugs, biologics, vaccines, medical devices, and other medical products as appropriate) in the region of the Americas.

FOR FURTHER INFORMATION CONTACT:

Management Contact: Katherine C. Bond, Office of International Programs, Office of the Commissioner, Food and Drug Administration, White Oak Bldg. 32, rm. 3300, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8318, FAX: 301–595–5058, email: *Katherine.Bond@fda.hhs.gov*.

Grants Contact: Kimberly Pendleton, Division of Acquisition and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2104, Rockville, MD 20857, 301–827–9363, FAX: 301–827–7101, email: *kimberly.pendleton@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please contact Kimberly Pendleton.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–10–009
Catalog of Federal Domestic Assistance Number(s): 93.103 *https://www.cfda.gov*

A. Background

FDA announces its intention to accept and consider a single source application to award a cooperative agreement to the PAHO for the development of an information hub in the areas of medical products and related regulatory processes and systems (e.g., including drugs, biologics, vaccines, medical devices, and other medical products as appropriate) in the region of the Americas.

B. Research Objectives

- The development of an online database (e.g., Web-based) in English and Spanish for a series of countries providing:
  - Overview of the regulated sector including description and specific data relating to the medical products and related regulatory processes and systems market;
  - Structural overview of the national regulatory process(es) including information relating to national entities participating in the regulatory process;
  - Data presented by specific regulatory areas (for example, biologics, vaccines, drugs, medical devices) on processes relating to product registration, licensing (manufacturer, wholesaler and pharmacy/vendor), quality control assessment and postmarketing surveillance;
  - Data presented on other regulatory areas such as clinical trials and supply chains;
  - Key regulations governing the areas of medical products and related regulatory processes and systems (e.g., including drugs, biologics, vaccines, medical devices, and other medical products as appropriate) per country and/or links to sources where such information is available.
  - Data collected and presented in such a way that ensures consistency of terminology, consistency in data collection methods, and robustness, comprehensiveness, and comparability of data.
- The establishment of information exchange mechanisms with the active participation of national regulatory agencies (NRAs) in the region of the Americas that facilitates the process by which the information hub and database is populated with information that is reviewed and maintained in an up-to-date and continual basis.
  - A detailed mechanism to maintain and update the hub information is developed detailing the responsibilities of PAHO and its Members States in keeping the data and information contained therein relevant, up-to-date, and comprehensive to encompass the future growth and complexity in the areas of medical products and related regulatory processes and systems.
- As appropriate, PAHO would work to align or link the information hub with other ongoing global initiatives of the World Health Organization (WHO) or its regional offices in regulatory aspects relating to medical products and related regulatory processes and systems.
- As appropriate, PAHO would work to enable effective linkage(s) of the information hub with other ongoing initiatives in regulatory aspects relating to medical products and related regulatory processes and systems including harmonization efforts, such as the Pan American Network for Drug Regulatory Harmonization (PANDRH), the ICH Global Cooperation Group; the Global Health Task Force on Health Technologies; the Asia-Pacific Economic Cooperation (APEC) harmonization efforts, and other relevant efforts and initiatives as appropriate.
- The utilization of the data and information contained within the information hub by NRAs to enable harmonized approaches, standards and guidelines for regulatory systems. It will support evidence-based decisionmaking by NRAs and regulated industry sectors, facilitate the exchange of timely and accurate data, and promote transparency of regulated approaches and efforts.

• As appropriate, explore with the WHO, the possibility of expanding this information hub to other WHO Regions.

C. Eligibility Information

The following organizations/institutions are eligible to apply: the PAHO.

II. Award Information/Funds Available

A. Award Amount

FDA anticipates providing one award of $904,000 (total costs including indirect costs) in FY 2010 in support of this project.

B. Length of Support

The support will be 1 year with the possibility of an additional 3 years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a non-competing continuation application and available Federal FY appropriations.

Dated: September 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24906 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0494]

Cooperative Agreement With the World Health Organization for a Plan to Develop a Global Integrated Food Safety Information Platform

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) announces its intention to accept and consider a single source application for awarding a cooperative agreement to the World Health Organization (WHO), Department of Food Safety and Zoonoses, to develop a plan for a global integrated food safety information system or platform in partnership with the WHO Secretariat and the Member States.

FOR FURTHER INFORMATION CONTACT:

Management Contact: Katherine C. Bond, Office of International Programs, Office of the Commissioner, Food and Drug Administration, White Oak Bldg. 32, rm. 3300, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–8318, FAX: 301–595–5058, email: *Katherine.Bond@fda.hhs.gov*.

Grants Contact: Kimberly Pendleton, Division of Acquisition and Grants (HFA–500), Food and Drug Administration, 5630 Fishers Lane, rm. 2104, Rockville, MD 20857, 301–827–9363, FAX: 301–827–7101, email: *kimberly.pendleton@fda.hhs.gov*.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please contact Kimberly Pendleton.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–10–009

Catalog of Federal Domestic Assistance Number(s): 93.103 *https://www.cfda.gov*

A. Background

FDA announces its intention to accept and consider a single source application for awarding a cooperative agreement to the WHO, Department of Food Safety and Zoonoses to develop a plan for a global integrated food safety information system or platform in partnership with the WHO Secretariat and the Member States. This project represents a collaborative agreement between WHO and FDA in support of global solutions to address food safety problems; global sharing of comparable food safety data and information; and improved global capacity for detection of and response to food safety threats through preventative controls, data and surveillance and risk-based approaches.

B. Research Objectives

• Outreach to parties who have information needs and information to share to ascertain their interests and to cultivate their support;

• Engagement of all relevant parties in defining the goals and designing the system to maximize utilization and sustainability;

• A timeline for development, design, pilot-testing, implementation and maintenance of a global integrated information platform;

• A business plan that delineates the commitment, support and resources of the WHO Secretariat and relevant stakeholders essential to ensure full implementation and long-term sustainability; and

• A clear articulation of the benefits, measurable outputs and impacts that would result from a WHO global integrated information platform to the global community, Member States and other relevant parties and stakeholders.

C. Eligibility Information

The following organizations/institutions are eligible to apply: The WHO.

II. Award Information/Funds Available

A. Award Amount

FDA anticipates providing one award of $395,500 (total costs including indirect costs) in fiscal year (FY) 2010 in support of this project.

B. Length of Support

The total project period for an application submitted in response to this funding opportunity may not exceed 1 year.

Dated: September 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24904 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–P–0338]

Determination That AZDONE (Hydrocodone Bitartrate and Aspirin) Tablet, 5 Milligrams/500 Milligrams, Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined that AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 milligrams (mg)/500 mg, was not withdrawn from sale for reasons of safety or effectiveness. This determination will allow FDA to approve abbreviated new drug applications (ANDAs) for hydrocodone bitartrate and aspirin tablet, 5 mg/500 mg, if all other legal and regulatory requirements are met.

FOR FURTHER INFORMATION CONTACT: Deborah Livornese, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 6306, Silver Spring, MD 20993–0002, 301–796–0719.

SUPPLEMENTARY INFORMATION: In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (Public Law 98–417) (the 1984 amendments), which authorized the approval of duplicate versions of drug products approved under an ANDA procedure. ANDA