

• 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]

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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]

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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