• 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

applicants must, with certain exceptions, show that the drug for which they are seeking approval contains the same active ingredient in the same strength and dosage form as the "listed drug," which is a version of the drug that was previously approved. ANDA applicants do not have to repeat the extensive clinical testing otherwise necessary to gain approval of a new drug application (NDA). The only clinical data required in an ANDA are data to show that the drug that is the subject of the ANDA is bioequivalent to the listed drug.

The 1984 amendments include what is now section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(7)), which requires FDA to publish a list of all approved drugs. FDA publishes this list as part of the "Approved Drug Products With Therapeutic Equivalence Evaluations," which is known generally as the "Orange Book." Under FDA regulations, drugs are removed from the list if the Agency withdraws or suspends approval of the drug's NDA or ANDA for reasons of safety or effectiveness or if FDA determines that the listed drug was withdrawn from sale for reasons of safety or effectiveness (21 CFR 314.162). Under § 314.161(a)(1) (21 CFR 314.161(a)(1)), the Agency must determine whether a listed drug was withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved. FDA may not approve an ANDA that does not refer to a listed drug.

AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, is the subject of ANDA 89–420, held by Schwarz Pharma, Inc., and initially approved on January 25, 1988. AZDONE is indicated for the relief of moderate to moderately severe pain. AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg is currently listed in the "Discontinued Drug Product List" section of the Orange Book.

Lachman Consultant Services, Inc., submitted a citizen petition dated June 23, 2010 (Docket No. FDA–2010–P–0338), under 21 CFR 10.30, requesting that the Agency determine whether AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, was withdrawn from sale for reasons of safety or effectiveness.

After considering the citizen petition and reviewing Agency records, FDA has determined under § 314.161 that AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg was not withdrawn for reasons of safety or effectiveness. The petitioner has identified no data or other information suggesting that AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, was withdrawn for reasons of safety or effectiveness. We have carefully reviewed our files for records concerning the withdrawal of AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, from sale. We have also independently evaluated relevant literature and data for possible postmarketing adverse events and have found no information that would indicate that this product was withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, in the "Discontinued Drug Product List" section of the Orange Book. The "Discontinued Drug Product List" delineates, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness. ANDAs that refer to AZDONE (hydrocodone bitartrate and aspirin) Tablet, 5 mg/500 mg, may be approved by the Agency as long as they meet all other legal and regulatory requirements for the approval of ANDAs. If FDA determines that labeling for this drug product should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: September 29, 2010.

David Dorsey,

Acting Deputy Commissioner for Policy, Planning and Budget.

[FR Doc. 2010–24902 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–0497]

Global Implementation of the Veterinary Medicinal Products Guidelines

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 a cooperative agreement to the World Organization for Animal Health (OIE). The OIE is the intergovernmental organization responsible for improving animal health worldwide and is recognized by the World Trade Organization (WTO) as a reference for international sanitary rules, with 175 Member Countries and Territories. The purpose of this agreement is to continue outreach that began in fiscal year (FY) 2009 to expand capacity building to support OIE's services and activities that are needed to carry out OIE's Veterinary International Conference on Harmonization (VICH) Global Outreach to disseminate and implement VICH guidelines at the country level.

FOR FURTHER INFORMATION CONTACT:

Program Contact: Merton V. Smith, Center for Veterinary Medicine (HFV–1), Food and Drug Administration, 7519 Standish Pl., rm. 177, Rockville, MD 20855, 240–276–9025, FAX: 240–276–9030, email: *Merton.Smith@fda.hhs.gov*.

Management Contact: Katherine C. Bond, 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–10–010

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 award of a cooperative agreement to the OIE in support of international technical capacity building activities that help to assure that U.S. imports of veterinary medicinal products are safe, effective, and of high quality and that food from treated animals is safe and wholesome; to assist foreign regulators in developing and using rigorous safety standards; to develop and foster mutually beneficial regulatory partnerships; and to leverage resources for capacity building through appropriate training and other activities.

B. Research Objectives

- Promote and enhance in OIE Members good veterinary governance, which includes the compliance of Veterinary Services with OIE