• 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 non-competitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a non-competitive continuation application and available Federal FY appropriations.


Leslie Kux,
Acting Assistant Commissioner for Policy.

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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

For more information on this funding opportunity, 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.

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, 10003 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.

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- 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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

For more information on this funding opportunity, 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

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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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

For more information on this funding opportunity, 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.

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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.


Leslie Kux,
Acting Assistant Commissioner for Policy.

For more information on this funding opportunity, 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.

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- 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.
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.


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 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