IV. Notice of Hearing Under 21 CFR Part 15

The Commissioner of Food and Drugs is announcing that the public hearing will be held in accordance with part 15 (21 CFR part 15). The hearing will be conducted by a presiding officer, who will be accompanied by FDA senior management from the Office of the Commissioner and the Center for Drug Evaluation and Research.

Under § 15.30(f), the hearing is informal and the rules of evidence do not apply. No participant may interrupt the presentation of another participant. Only the presiding officer and panel members may question any person during or at the conclusion of each presentation. Public hearings under part 15 are subject to FDA's policy and procedures for electronic media coverage of FDA's public administrative proceedings (part 10, subpart C (21 CFR part 10, subpart C)). Under § 10.205, representatives of the electronic media may be permitted, subject to certain limitations, to videotape, film, or otherwise record FDA's public administrative proceedings, including presentations by participants. The hearing will be transcribed as stipulated in § 15.30(b) (see section VI of this document). To the extent that the conditions for the hearing, as described in this notice, conflict with any provisions set out in part 15, this notice acts as a waiver of those provisions as specified in § 15.30(h).

V. Request for Comments

Regardless of attendance at the public hearing, interested persons may submit either electronic or written comments to the Division of Dockets Management (*see* **ADDRESSES**). It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VI. Transcripts

Transcripts of the public hearing will be available for review at the Division of Dockets Management (*see* **ADDRESSES**) and on the Internet at http://www.regulations.gov approximately 30 days after the public hearing. A transcript will also be made available in either hard copy or on CD–ROM, upon submission of a Freedom of Information request. Written requests are to be sent to Division of Freedom of Information (HFI–35), Office of Management Programs, Food and Drug Administration, 5600 Fishers Lane, Room 6–30, Rockville, MD 20857.

Dated: September 29, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010–24853 Filed 10–4–10; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0496]

Cooperative Agreement To Support Capacity Building Activities Through the World Health Organization Global Foodborne Infections Network

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application to award a cooperative agreement to the World Health Organization (WHO) Advisory Group on Integrated Surveillance of Antimicrobial Resistance (AGISAR) and in support of the WHO Global Foodborne Infections Network (GFN) and to provide guidance to the WHO on a framework for the development of an international network to promote and enhance collaboration on harmonization and data sharing among countries with Antimicrobial Resistance (AMR) surveillance programs.

FOR FURTHER INFORMATION AND ADDITIONAL REQUIREMENTS CONTACT:

Program Contact: Patrick McDermott, Division of Animal and Food Microbiology, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Mod II, rm. 1505, Rockville, MD 20855, 301–210–4213, FAX: 301–210–4685, email: *Patrick.McDermott@fda.hhs.gov*.

Management Contact: Katherine C. Bond, Office of International Programs, Office of the Commissioner, FDA, 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, FDA, 5630 Fishers Lane (HFA–500), 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–10–006]

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

A. Background

The Food and Drug Administration (FDA) is announcing its intention to accept and consider a single source application for a cooperative agreement to the WHO GFN. This project represents a collaborative agreement between the WHO and FDA aimed at capacity building in laboratory based surveillance of foodborne pathogens and disease in developing regions to support AGISAR and GFN to enable FDA to realize its goal of developing an international database for human and animal isolates of foodborne pathogens and their susceptibility profiles.

B. Research Objectives

- Support WHO capacity building activities with member countries for AMR monitoring (development of AMR training modules for GFN training courses, and hosting of visiting scientist from developing countries).
- Develop harmonized schemes for monitoring antimicrobial resistance in zoonotic and enteric bacteria to include appropriate sampling.
- Promote information sharing on AMR (development of a global AMR databank).
- Provide expert advice to WHO, and promote WHO and FDA collaborative work to advise WHO Member States on containment of AMR with a particular focus to Human Critically Important Antimicrobials. AGISAR should be the core advisory group to review criteria for ranking human and animal antimicrobials to be reviewed by WHO; and FDA's resources could be used in support of AGISAR's participation.
- Support and advise WHO on selection of sentinel sites to be strategically identified around the globe and designing pilot projects to conduct integrated surveillance of antimicrobial resistance.
- Promote development of standardized methods for monitoring antimicrobial use and work with member states for the implementation of these methods at the country-level.
- Promote the development of published articles on the emergence of AMR threats and challenges, and the

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.