management; and making the business case for investments in regulatory systems.

C. Eligibility Information

This is a Single Source Cooperative Agreement.

II. Award Information/Funds Available

A. Award Amount

An award of up to $1,500,000 for this cooperative agreement will be available the first year (fiscal year (FY) 2013) based on available appropriations. Funding for subsequent years for this 5-year award will be contingent on the availability of appropriations and successful performance in the award not to exceed $1,500,000 per year.

B. Length of Support

The initial period of performance is 1 year. Contingent upon successful performance, additional awards may be available in FYs 2014, 2015, 2016, and 2017.

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://www.fda.gov/InternationalPrograms/CapacityBuilding/default.htm.* (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

- Step 1: Obtain a Dun and Bradstreet (DUNS) Number
- Step 2: Register With System for Award Management (SAM)
- Step 3: Obtain Username & Password
- Step 4: Obtain Authorized Organization Representative (AOR) Authorization
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- Step 6: Register With Electronic Research Administration (eRA) Commons

Steps 1 through 5, in detail, can be found at *http://www07.grants.gov/applicants/organization_registration.jsp.* Step 6, in detail, can be found at *https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp.* After you have followed these steps, submit electronic applications to: *http://www.grants.gov.*

Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0012]

Building Research Capacity in Global Tobacco Product Regulation Program (U18)

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for the support of the Center for Tobacco Product's (CTP's) Building Research Capacity in Global Tobacco Product Regulation Program. FDA intends to accept and consider a single source application for award to the World Health Organization (WHO) to identify, support, develop, conduct, and coordinate research efforts relating to tobacco control laws and rules in foreign countries that will directly inform and support FDA's exercise of its authority to regulate the manufacture, distribution, marketing, and sale of tobacco products in the United States. The Building Research Capacity in Global Tobacco Product Regulation Program seeks to advance and expand research in support of tobacco product regulation, in order to reduce the morbidity and mortality associated with tobacco use both within the United States and internationally. The program will advance FDA's and CTP's mission by utilizing WHO Member States' expertise and extensive international contacts in global tobacco control, as well as WHO's own programmatic expertise, to inform and support adequate manufacture, distribution, and market regulations of tobacco products for the protection of public health in the United States.

DATES: Important dates are as follows:

1. The application due date is July 31, 2013.
2. The anticipated start date is September 2013.
3. The opening date is July 1, 2013.
4. The expiration date is August 1, 2013.

ADDRESSES: Submit electronic applications to: *http://www.grants.gov.* For more information, see section III of the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Caitlin Addorisio, Center for Tobacco Products, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–796–0371; or Lisa Ko, Office of Acquisition and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 301–827–5095.

For more information on this funding opportunity announcement (FOA) and to obtain detailed requirements, please refer to the full FOA located at *http://www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–13–032.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–13–032.
93.103.

A. Background

1. Authority

The Building Research Capacity in Global Tobacco Product Regulation Program is authorized by 42 U.S.C. 241 of the Public Health Service Act and the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31).

2. Program Background

Tobacco use is the foremost preventable cause of premature death in America. It causes over 443,000 deaths in the United States each year, and another 8.6 million smokers have at least one serious illness due to smoking. A compelling body of evidence illustrates that tobacco products are inherently dangerous and cause cancer, heart disease, and other serious adverse health effects.

On June 22, 2009, President Obama signed the Tobacco Control Act, giving FDA regulatory authority to regulate the manufacturing, labeling, sale, distribution, advertising, and promotion of tobacco products.

Some key FDA activities authorized or required by the Tobacco Control Act include:

- Mandating larger, more varied, and more prominent warning labels on cigarette and smokeless tobacco products (Title II of the Tobacco Control Act).
- Restricting tobacco product sales, advertising, and promotion (section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 387f(d)); section 102 of the Tobacco Control Act)).
- Establishing product standards to regulate the contents, design, components, emissions, and other characteristics of tobacco products

(section 907 of the FD&C Act) (21 U.S.C 387g).

- Prohibiting explicit and implicit claims of modified risk or modified exposure (including ''light,'' ''low,'' or ''mild'' and similar descriptors), without an FDA order that the modified risk product may be marketed (section 911 of the FD&C Act) (21 U.S.C. 387k).
- In general (with certain narrow exceptions), limiting the introduction of new tobacco products to those for which FDA determines that the marketing of the product would be ''appropriate for the protection of public health'' (sections 905, 910 of the FD&C Act) (21 U.S.C. 387e, 387j).
- Collecting data on certain tobacco product constituents, ingredients, and additives and establishing a list of harmful and potentially harmful constituents in tobacco products, including smoke constituents, by brand and subbrand (sections 904, 915 of the FD&C Act) (21 U.S.C. 387d, 387*o*).

Please visit *http://www.fda.gov/TobaccoProducts/default.htm* for more information on the Tobacco Control Act and related regulations, guidance, and other educational information.

To implement the new law, Congress directed the creation of CTP at FDA. CTP oversees the implementation of the Tobacco Control Act. CTP's mission is to protect Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products and by educating the public, especially young people, about tobacco products and the dangers their use poses to themselves and others.

Protecting the public health requires multidimensional programs that address both immediate threats as well as their systemic causes. Using this public health approach, CTP can successfully deter youth from ever using tobacco products while encouraging current consumers to quit. CTP will communicate broadly and effectively about the Agency's new responsibilities for tobacco product regulation and the dangers tobacco use poses to young people and adults. CTP will use its unique authorities to develop strategies to decrease the harms associated with the use of tobacco products. CTP will expand its research program and, with it, its proven commitment to regulatory science.

CTP's strategic public health goals include:

- Decreasing initiation of tobacco product use, especially among youth,
- Decreasing the harms of tobacco product use, and
- Encouraging tobacco use cessation.

3. Overarching Program Goal

The goal of the Building Research Capacity in Global Tobacco Product Regulation Program is to advance and expand research in support of tobacco product regulation, in order to reduce the morbidity and mortality associated with tobacco use both within the United States and internationally.

WHO, in particular WHO's Tobacco Free Initiative, will conduct and coordinate data collection, expert insights and analysis, and other research to support tobacco product regulation activities. WHO's activities provide a universal public health benefit by identifying and analyzing tobacco regulatory challenges, collating science-based tools to combat such challenges, and enhancing regulatory capabilities of governments to implement successful tobacco product regulation and decrease the global use of tobacco products. The activities provide a significant domestic benefit, as the scientific, policy, and legal research gathered will contribute to FDA's own tobacco product regulation activities aimed at decreasing domestic tobacco-related death and disease, and the American public will gain new information about tobacco products and the dangers their use poses.

As highlighted previously, CTP continues to take steps to implement the Tobacco Control Act. It is beneficial for FDA to learn from the successes and failures of other international regulatory agencies and consider the vast research available globally to inform FDA's decisions. As CTP considers its mandate to place restrictions on the sale and distribution of tobacco products, implement tobacco product standards, review applications for new tobacco products, and consider applications for modified risk products, among other activities, it is important to consider global trends, scientific literature, and the support/scientific information/research or evaluation opportunities in other countries' relevant tobacco experience. The Building Research Capacity in Global Tobacco Product Regulation Program will help support a global network of tobacco product regulators that will enable robust information sharing and health research collection globally, thereby catalyzing the use of best practices, and complementing CTP's regulatory efforts.

B. Research Objectives

1. Program Purpose

The purpose of the Building Research Capacity in Global Tobacco Product Regulation Program is to identify, support, develop, conduct, and coordinate research efforts relating to tobacco control laws and rules in foreign countries that will directly inform and support FDA's exercise of its authority to regulate the manufacture, distribution, marketing, and sale of tobacco products in the United States.

The program will advance CTP's mission by utilizing the WHO's Member States' expertise and extensive international contacts in global tobacco control, as well as WHO's own programmatic expertise, to inform and support adequate manufacture, distribution, and market regulations of tobacco products for the protection of public health in the United States.

2. Program Priorities

The Program's grant funds will support WHO in expanding the research foundation for tobacco product regulation, in an effort to support FDA's implementation of the Tobacco Control Act. It is expected that this effort may also support foreign governments' development of tobacco control policies and regulations. A strong application will seek to increase comprehensive data collection, expert insight and analysis, and other research related to scientific, legal, and policy information that can contribute to successful domestic regulation and policies that will protect Americans from tobacco-related death and disease and promote public understanding of tobacco risk.

The application must include the following activities: (1) Propose a program plan, relying on WHO's long history of coordinating international collaborative projects in support of tobacco control development and its established international contacts, that supports FDA approaches to reducing tobacco use, harm, and addiction; (2) identify, support, develop, conduct, and coordinate multilateral research efforts in the areas of science, law, policy, and public health communications/education that advance FDA's regulation of the manufacturing, marketing, and distribution of tobacco products as found in the Tobacco Control Act; (3) plan, build, adapt, or expand data collection/information sharing mechanisms, management, and reporting protocols necessary to facilitate Program information exchanges, analysis, and other research; and (4) evaluate program activities, processes, and outcomes, including summation evaluation, to document and disseminate results and outcomes.

The applicant must propose science-based activities that advance the international tobacco product regulation research foundation in order to reduce tobacco-related death and disease both

in the United States and around the world. The applicant should track both short-term and long-term goals, and demonstrate how the proposed activities are related to CTP's regulation of tobacco products under the Tobacco Control Act.

By way of example, project activities could:

- In the first year, draft a long-term strategy for increasing WHO's capacity to facilitate global tobacco-related research;
- Create global data information systems to support the program research goals and allow for efficient and timely information sharing with FDA and other partners;
- Continue to coordinate and mobilize an international tobacco regulators' network, via conferences, workshops, teleconferences, and other regular engagements, for the purpose of sharing global tobacco regulation experience and expertise; and
- Analyze tobacco-related research and produce technical papers on various issues of relevance to tobacco product regulation, e.g., illicit trade in tobacco products, tobacco control and intellectual property rights, tobacco control and international trade, nicotine addiction, and other topics.

The applicant must be familiar with the specific provisions of the Tobacco Control Act and the regulatory activities of FDA. In addition to demonstrating how the proposed project is related to CTP's regulation of tobacco products under the Tobacco Control Act, the applicant must demonstrate how it will advance the public health goals that underlie these FDA activities. Please visit *http://www.fda.gov/TobaccoProducts/default.htm* for more information on the Tobacco Control Act and related regulations, guidance, and other educational information.

C. Eligibility Information

The following organization is eligible to apply: WHO.

As FDA seeks to proactively work with other countries and identify research and evaluation opportunities that will impact FDA's ability to successfully implement the Tobacco Control Act, further collaboration with WHO is anticipated. With the financial support from FDA, WHO is uniquely qualified to undertake these activities, given its mandate, wide access to data, participation of member states, and access to worldwide regulatory expertise.

Specific Evidence To Justify Single Eligibility

- Example databases already in place:
  - WHO Framework Convention on Tobacco Control Health Warnings Database (*http://www.who.int/tobacco/healthwarningsdatabase/en/index.html*).
  - Tobacco Industry Monitoring Database.
- Examples of Global Tobacco Research Reports/White Papers:
  - WHO report on the global tobacco epidemic, 2001, 2009, 2008.
  - Developing Legislation for Tobacco Control.
  - WHO Study Group on Tobacco Product Regulation Report on the Scientific Basis of Tobacco Product Regulation.
  - Confronting the tobacco epidemic in a new era of trade and investment liberalization.
  - See more examples at: *http://www.who.int/tobacco/publications/prod_regulation/en/index.html.*
- Examples of Global Tobacco Regulator Workshops and Meetings/Network of Scientists:
  - Tobacco Product Regulation (TobReg): *http://www.who.int/tobacco/industry/product_regulation/tobreg/en/index.html.*
  - Tobacco Laboratory Network (TobLabNet): *http://www.who.int/tobacco/industry/product_regulation/toblabnet/en/index.html.*
  - Experience coordinating and conducting regular scientific meetings: *http://www.who.int/tobacco/industry/product_regulation/toblabnet/meetings/en/index.html.*
  - 2011 International Tobacco Regulators Conference that was cosponsored by WHO and FDA: *http://www.who.int/tobacco/industry/product_regulation/forum/conference2012.pdf.*

II. Award Information/Funds Available

A. Award Amount

FDA/CTP anticipates providing in fiscal year (FY) 2013 up to $1 million (total costs including indirect costs for one award subject to availability of funds) in support of this project. FDA/CTP anticipates the possibility of four additional years of support up to $4 million of funding contingent upon successful performance and the availability of funding. Program funds may not be used for any purpose other than those directly tied to the regulation of tobacco products under the Tobacco Control Act.

- FY Funds: 2013.
- Estimated Current FY Funding: $1 million.
- Maximum Size Award in Current Fiscal Year: $1 million.
- Estimated Number of Awards: 1.
- Estimated Future Year Funding: FY 2014 ($1 million), FY 2015 ($1 million), FY 2016 ($1 million), and FY 2017 ($1 million).
- Maximum Size Award in Future Years: FY 2014 ($1 million), FY 2015 ($1 million), FY 2016 ($1 million), and FY 2017 ($1 million).
- Maximum Project Period: 5 Years.

B. Length of Support

The length of support will depend on the nature of the project. The budget period in current and future funding years will be as follows: FY 2013 (12 months), FY 2014 (12 months), FY 2015 (12 months), FY 2016 (12 months), and FY 2017 (12 months).

III. Electronic Application, Registration, and Submission

Only electronic applications will be accepted. To submit an electronic application in response to this FOA, applicants should first review the full announcement located at *http://www.grants.gov.* Search by Funding Opportunity Number: RFA–FD–13–032. (FDA has verified the Web site addresses throughout this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.) For all electronically submitted applications, the following steps are required.

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Dated: June 19, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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