cooperative agreement with the U.S. Department of Education, Rehabilitation Services Administration. The Department of Health and Human Services is currently transitioning programs under the *AT Act* to ACL.

DATES: Estimated Project Period—September 30, 2015 through September 30, 2016

SUPPLEMENTARY INFORMATION:

Program Name: Assistive Technology National Activities.

Award Amount: $640,000 to Rehabilitation Engineering and Assistive Technology Society of North America; $100,000 to University of New Hampshire Institute on Disability.

Project Period: 9/30/2015 to 9/30/2016.

Award Type: Cooperative Agreement.

Statutory Authority: This program is authorized under Section 6 of the *Assistive Technology Act of 1998,* as amended (29 U.S.C. 3005)

Catalog of Federal Domestic Assistance (CFDA) Number: 93.464 Discretionary Projects

Program Description

The purpose of the National Activities cooperative agreements with RESNA and the University of New Hampshire is to continue existing activities designed to support and improve the administration of the *AT Act.* The grantees will continue to use both traditional and innovative approaches that will assist individuals and entities through information dissemination and provide state-specific, regional and national training and technical assistance concerning assistive technology.

Justification: ACL is currently working on transitioning the Assistive Technology National Activities program to ACL. To ensure uninterrupted continuation of the grant goals and objectives, ACL plans to issue a one year non-competing award to both RESNA and the University of New Hampshire.

FOR FURTHER INFORMATION CONTACT: For further information or comments regarding this action, contact Lori Gerhard, U.S. Department of Health and Human Services, Administration for Community Living, Center for Consumer Access and Self-Determination, Office of Integrated Programs, One Massachusetts Avenue NW., Washington, DC 20001; telephone (202) 357–3443; fax (202) 357–3469; email *Lori.Gerhard@acl.hhs.gov.*

Dated: May 13, 2015.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2015–11961 Filed 5–15–15; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0012]

Cooperative Agreement to International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use

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 International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). The goal of the ICH is to bring together leading global drug regulatory agencies and pharmaceutical manufacturer associations to achieve greater harmonization of technical standards to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.

DATES: The application due date is September 30, 2015. The expiration date is October 1, 2015.

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: Tracy Porter, Office of Strategic Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1173, Silver Spring, MD 20993, 301–796–7789, *Tracy.Porter@fda.hhs.gov*; or Lisa Ko, Office of Acquisitions and Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rm. 2037, Rockville, MD 20857, 240–402–7592, *Lisa.Ko@fda.hhs.gov.*

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–15–014.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–15–014

93.103

A. Background

1. Authority

FDA activities to increase the harmonization of regulatory requirements to ensure that safe, effective, and high quality medicines are developed and registered in the most resource-efficient manner are authorized by 21 U.S.C. 383(c) and 393(b).

2. Program Background

The ICH is a globally unique venue with the capability of bringing together the regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of drug registration. ICH is a programmatic global priority for FDA to achieve its identified strategic priority of globalization. Working through its Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research, FDA has played a leading role in ICH since its inception in 1990. ICH, founded to harmonize drug regulatory standards between three regions, the United States, the European Union, and Japan, has gradually evolved to respond to the increasingly global face of drug development, so that the benefits of international harmonization for better global health can be realized worldwide. ICH's mission is to achieve greater harmonization to ensure that safe, effective, and high-quality medicines are developed and registered in the most resource-efficient manner.

Over the past 2 years, FDA played a leadership role in transforming ICH to meet the challenges of 21st century standards development while firmly positioning ICH future work to continue the focus on technical standards harmonization informed by relevant expertise from regulatory agencies and regulated industry. This effort has included: (1) Establishing ICH as a formal legal entity in the form of a nonprofit association under Swiss law; (2) expanding the opportunities for formal participation of other drug regulatory authorities beyond the three founding regions via the ICH Assembly; and (3) ensuring adequate and predictable funding for the ICH harmonization work (which is also critical to FDA's mission).

FDA remains an ICH founding member and completely committed to ICH success as a science-based standards development venue to ensure harmonization globally for safe, effective, and high-quality medicines. As exemplified in the past 25 years, FDA leadership and participation is an

absolutely essential element for ICH success.

B. Research Objectives

The program's grant funds will support the ICH to develop a series of international guidelines for implementation according to each region's requirements aimed at achieving the following: (1) Develop and register safe, effective, and high quality medicines in the most efficient and cost effective manner; (2) prevent unnecessary duplication of clinical trials and minimize the use of animal testing without compromising safety and effectiveness, and (3) provide public assurance that the rights, safety, and well-being of subjects are protected during clinical trials.

The ICH aims to make information readily available on ICH, ICH activities, and ICH guidelines to any country or company that requests the information. Additionally, the organization promotes a mutual understanding of regional initiatives in order to facilitate harmonization processes related to ICH guidelines regionally and globally, and to strengthen the capacity of drug regulatory authorities and industry to utilize the guidelines. These objectives will be accomplished by bringing together representatives from both regulatory agencies and pharmaceutic industries from the three founding regions to establish guidelines.

C. Eligibility Information

The following organization is eligible to apply: ICH. Within the ICH, the mission is to make recommendations towards achieving greater harmonization in the interpretation and application of technical guidelines and requirements for pharmaceutical product registration, thereby reducing or obviating duplication of testing carried out during the research and development of new human medicines. Leveraging its status as a neutral nonprofit entity focused on technical standards harmonization, the ICH aims to promote international harmonization of drug regulatory standards by bringing together representatives from both regulatory agencies and pharmaceutic industry to discuss and establish common guidelines.

II. Award Information/Funds Available

A. Award Amount

FDA intends to fund one award, corresponding to a total of up to $500,000, for fiscal year (FY) 2016. Future year amounts will depend on annual appropriations, availability of funding, and awardee performance. CDER anticipates providing four additional years of support up to the following amounts:

FY 2017: $500,000

FY 2018: $500,000

FY 2019: $500,000

FY 2020: $500,000

B. Length of Support

The support will be 1 year with the possibility of an additional 4 years of noncompetitive support. Continuation beyond the first year will be based on satisfactory performance during the preceding year, receipt of a noncompeting continuation application and available Federal FY appropriations.

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.* (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**.) Search by Funding Opportunity Number: RFA–FD–15–014.

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: Authorized Organization Representative (AOR) Authorization
- Step 5: Track AOR Status
- 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: May 11, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11847 Filed 5–15–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–1377]

Electronic Study Data Submission; Data Standards; Study Data Standardization Plan Recommendations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft recommendations for preparing a Study Data Standardization Plan (Standardization Plan). The Standardization Plan is referenced in the Study Data Technical Conformance Guide (Guide). The Guide supplements the guidance for industry ''Providing Regulatory Submissions in Electronic Format—Standardized Study Data'' and provides specifications, recommendations, and general considerations on submitting standardized study data using FDA-supported data standards. The Guide recommends that, for clinical and nonclinical studies, sponsors include a plan that describes the submission of standardized study data to FDA. The proposed recommendations describe the information that should be included in the Standardization Plan. The proposed recommendations for creating a Standardization Plan are posted on FDA's Study Data Standards Resources Web page at *http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm.*

DATES: Although you can comment on these recommendations at any time, to ensure that the Agency considers your comments, please submit either electronic or written comments by July 2, 2015.

ADDRESSES: Submit written requests for single copies of the recommendations to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit electronic comments to *http://www.regulations.gov.* Submit