The guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents FDA’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). None of the collections of information referenced in this guidance are new or represent material modifications to previously approved collections of information. The collections of information under 21 CFR part 312 have been approved under OMB control number 0910–0078; the collections of information under 21 CFR part 314 have been approved under OMB control number 0910–0053; and the collections of information under 21 CFR parts 201, 202, 203, and 204 have been approved under OMB control number 0910–0079.

III. Comments

Interested persons may submit either electronic comments regarding this guidance to http://www.regulations.gov or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of 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, and will be posted to the docket at http://www.regulations.gov.

IV. Electronic Access

Persons with access to the Internet may obtain the document at http://www.regulations.gov or http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/GuidancesInformationSheetsandNotices/ucm219433.htm.

Dated: August 21, 2013.

Leslie Kux,
Assistant Commissioner for Policy.
The CFAST Initiative aims to accelerate clinical research and medical product development by establishing and maintaining data standards, tools, and methods for conducting research in therapeutic areas that are important to public health. It is established as a public-private partnership (PPP) involving multiple stakeholders. The Grantee funded through this announcement would be expected to accomplish activities such as, but not limited to:

- Maintenance of the scientific and administrative infrastructure of the PPP to support a series of projects under the CFAST Initiative.
- Coordination and management of therapeutic area standards development projects with key experts in the specific therapeutic areas, including stakeholders from industry, professional organizations, academia, and Government agencies.
- Development of therapeutic area data standards, initially proposed for diabetes, QT studies, lipid lowering/altering drugs, and hepatitis C. Additional or different areas can be considered as well.
- Identification and implementation of continuous quality improvements with respect to the data standards development process and product(s) to facilitate timely and sustainable standards.

C. Eligibility Information

The following organization is eligible to apply: The Critical Path Institute (C-Path).

Over the past 7 years, C-Path has become an international leader in forming and leading/managing collaborations globally. They currently lead 7 very active scientific consortia across multiple disease areas. C-Path consortia include more than 1,000 scientists from Government, academia, patient advocacy organizations, and 41 major pharmaceutical companies. C-Path has a proven process, capability, and institutional knowledge critical to successfully leading scientific consortia and rapid therapeutic area standards development projects through an open, transparent process as identified by the Prescription Drug User Fee Act V.

II. Award Information/Funds Available

A. Award Amount

Total amount of funding available is $2,000,000. Anticipate one award.

B. Length of Support

Scope of the proposed project should determine the project period. The maximum period is 3 years.

III. Paper Application, Registration, and Submission Information

To submit a paper application in response to this FOA, applicants should first review the full announcement located at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm364432.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.) Persons interested in applying for a grant may obtain an application at http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm364432.htm. For all the paper application submissions, 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: Register With Electronic Research Administration (eRA) Commons

Steps 1 and 2, in detail, can be found at http://www07.grants.gov/applicants/organization_registration.jsp. Step 3, in detail, can be found at https://commons.era.nih.gov/commons/registration/registrationInstructions.jsp. After you have followed these steps, submit paper applications to: Kimberly Pendleton-Chew, 5630 Fishers Lane, Rm. 2031, Rockville, MD 20857, 301–827–9363, email: Kimberly.Pendleton@fda.hhs.gov.

Dated: August 21, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

[FR Doc. 2013–20823 Filed 8–26–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for