TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Total					338

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 30 minutes.

The estimate of the number of firms that will submit new written requests to be placed on the list, biennial updates, and occasional updates is based on the FDA's experience maintaining the list over the past 8 years. The estimate of the number of hours that it will take a firm to gather the information needed to be placed on the list or update its information is based on FDA's experience with firms submitting similar requests. FDA believes that the information to be submitted will be readily available to the firms.

Based on submissions received for the Chile list over the past 3 years and the China list over the past 3 months, we estimate that, annually, an average of 100 new firms will submit written requests to be placed on the China list and 25 new firms will seek to be placed on the Chile list, reported as 125 total respondents on line 1 of table 1. We estimate that a firm will require 1.5 hours to read the guidance, to gather the information needed, and to prepare a communication to FDA that contains the information and requests that the firm be placed on the list, for a total of 187.5 burden hours, rounded to 188, as reported on line 1 of table 1. Under the guidance, every 2 years each firm on the list must provide updated information in order to remain on the list.

There are approximately 250 firms on the 2 lists combined. We estimate that, each year, approximately half of the firms on the list, 125 firms, will resubmit the information to remain on the list. We estimate that a firm already on the list will require 1 hour to biennially update and resubmit the information to us, including time reviewing the information and corresponding with us, for a total of 125 hours. In addition, we expect that, each year, approximately 50 firms will need to submit an occasional update and each firm will require 0.5 hour to prepare a communication to us reporting the change, for a total of 125 hours.

Dated: May 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11927 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0485]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 23, 2014.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the title ''Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Electronic Submission Process for Voluntary Allegations to the Center for Devices and Radiological Health—(OMB Control Number 0910–NEW)

This information collection request collects information voluntarily submitted to the Center for Devices and Radiological Health (CDRH) on actual or potential health risk concerns about a medical device or radiological product or its use. Because there has been no established guidelines or instructions on how to submit an allegation to CDRH, allegations often contain minimal information and are received via phone calls, emails, or conversationally from any CDRH staff. CDRH seeks to establish a consistent format and process for the submission of device allegations that will enhance our timeliness in receiving, assessing and evaluating voluntary allegations. The information provided in the allegations received by CDRH may be used to clarify the recurrence or emergence of significant device-related risks to the general public and the need to initiate educational outreach or regulatory action to minimize or mitigate identified risks.

In the **Federal Register** of May 6, 2013 (78 FR 26373), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN[1]

Allegation reporting respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
	700	1	700	[2].25	175

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] 15 minutes.

Dated: May 16, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11922 Filed 5–22–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0610]

Increasing the Quality and Efficiency of Clinical Trials

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 efforts of the Center for Drug Evaluation and Research/Office of Medical Policy to increase the quality and efficiency of clinical trials. The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), Office of Medical Policy is announcing its intent to accept and consider a single-source application for the award of a grant to the Duke University's Duke Translational Medicine Institute (DTMI).

DATES: The application due date is June 30, 2014, by 11:59 p.m. Eastern Time. The expiration date is July 1, 2014.

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: Mark Lauda, Office of Medical Policy, Center for Drug Evaluation and Research, Food and Drug Administration, 10990 New Hampshire Ave., Bldg. 51, Rm. 2212, Silver Spring, MD 20993, 301–796–0381, email: *Mark.Lauda@fda.hhs.gov;* or Lisa Ko, Office of Acquisition & Grants Services, Food and Drug Administration, 5630 Fishers Lane, Rockville, MD, 240–402–7592, email: *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–14–017.

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

RFA–FD–14–017
93.103

A. Background

It has long been recognized that the clinical trial enterprise will need to evolve in order to meet the demand to provide data to support evidence-based decisionmaking. A memorandum of understanding (MOU) between FDA and Duke University published in the **Federal Register** on November 23, 2007, served as the basis for the establishment of the Clinical Trials Transformation Initiative (CTTI). CTTI is a public-private partnership whose mission is to identify and promote practices that will increase the quality and efficiency of clinical trials. This award will be made to DTMI within Duke University to identify and implement projects and disseminate resulting findings that will increase the quality and efficiency of clinical trials, CTTI's mission.

CTTI membership is broad and includes stakeholders from government, industry, patient advocacy and consumer groups, professional societies, clinical research organizations, and academia. CTTI helps to effect change through the conduct of projects that identify existing inefficiencies, elucidate superior practices, and/or provide innovative approaches to evidence generation and medical product development. CTTI conducts projects that are either: (1) Proposed by its member organizations, including FDA, developed during review by its Steering Committee, and endorsed by its Executive Committee or (2) responsive to urgent needs of FDA.

The opportunity for meaningful interaction with a broad set of stakeholders committed to improving the clinical trial enterprise and also the ability to rapidly gather data to address emerging issues offer significant value to the clinical trial enterprise. Since its inception, CTTI has undertaken many projects that have direct relevance to FDA's mission, including investigational new drug (IND) safety reporting, clinical trial monitoring, use of central investigational review boards, and antibacterial drug development.

B. Research Objectives

The goals of this program are to develop and maintain an administrative and scientific infrastructure to support the creation and execution of a series of projects under the auspices of CTTI that will increase the quality and efficiency of clinical trials. The following are examples of activities that could be supported by this grant:

- Maintaining an adequate administrative and scientific infrastructure to implement all related projects under this collaborative effort.
- Identifying and/or hiring a sufficient number of qualified personnel to conduct activities, including project management, such as review of project milestones for degree of completion, preparation/reporting of project findings, periodic and final reports, and for subsequent distribution in the public domain.
- Developing plans for the conduct of identified projects.
- Identifying, securing, and/or building, and effectively leveraging other resources for the conduct of identified projects.
- Upon completion of a given project, generating project results and recommendations and proposing related studies/projects, if needed, to build on the findings of the project and continuing to leverage established resources and personnel.

C. Eligibility Information

The following organization is eligible to apply: DTMI located within Duke University.

II. Award Information/Funds Available

A. Award Amount

This is a multiyear grant. FDA/CDER intends to fund up to $7,500,000 in total costs (direct and indirect) in Fiscal Year 2014. Awards are contingent upon the availability of funds.

Subject to the availability of Federal funds and successful performance of the FOA's stated goals and objectives, four additional years of support may be