Through the pilot test, we will determine the response rate that can be achieved using this approach. If it is deemed necessary, a prenotification letter, additional mailout reminders and a telephone non-response step can be added to the protocol to achieve desired response rate. *Form Number:* CMS–10393 (OMB Control number: 0938–1177); *Frequency:* Once; *Affected Public:* Individuals or households; *Number of Respondents:* 16,010; *Number of Responses:* 16,010; *Total Annual Hours:* 4,002. (For policy questions regarding this collection, contact Coles Mercier at 410–786–2112.)

Dated: July 16, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–17824 Filed 7–20–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Form CB–496, ''Title IV–E Programs Quarterly Financial Report''

OMB No.: 0970–0205

Description: This is a financial report submitted following the end of each fiscal quarter by each State or Tribe with an approved title IV–E plan administering any of three title IV–E entitlement grant programs—Foster Care, Adoption Assistance or Guardianship Assistance.

The purpose of this form is to enable each State or Tribe to meet its statutory and regulatory requirement to report program expenditures made in the preceding fiscal quarter and to estimate program expenditures to be made in the upcoming fiscal quarter. This form also allows States and Tribes to report the actual and estimated average monthly number of children assisted in each of the three IV–E entitlement grant programs in the preceding and upcoming fiscal quarters, respectively.

The Administration for Children and Families provides Federal funding at the rate of 50 percent for nearly all allowable and legitimate administrative costs of these programs and at other funding rates for other specific categories of costs as detailed in Federal statute and regulations. The information collected in this report is used by this agency to calculate quarterly Federal grant awards and to enable oversight of the financial management of the programs. Legislation enacted in 2014 through Public Law 113–183, the ''Preventing Sex Trafficking and Strengthening Families Act'' added a requirement that title IV–E grantees annually report on the methodology used to calculate adoption savings due to the application of differing title IV–E Adoption Assistance eligibility criteria for children designated as an ''applicable child'' along with an accounting of the amount of and the expenditure of any such savings.

To accommodate this change in the law, we have added additional data entry lines in part 4 of Form CB–496, ''Annual Adoption Savings Calculation and Accounting Report'' which will be submitted annually by grantees.

In addition, the same law adds additional requirements that title IV–E grantees develop and implement policies and procedures to identify, document, and determine appropriate services for any child or youth in the placement, care or supervision of the title IV–E agency who is at-risk of becoming a sex trafficking victim or who is determined as a sex trafficking victim.

To accommodate this change in the law we have added additional reporting lines and prior quarter reporting odes for expenditure reporting and child counts and in parts 1 and 2 of Form CB–496.

Respondents: States (including Puerto Rico and the District of Columbia) and Tribes* with approved title IV–E plans. (*An estimated 15 Tribes have or will have approved title IV–E plans within the next 3-year period.)

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form CB–496: Title IV–E Programs Quarterly Financial Report	67	4	21	5,628

Estimated Total Annual Burden Hours: 5,628.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–17793 Filed 7–20–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2000–D–0067]

Medical Device Patient Labeling; Request for Comments; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration is announcing the following public workshop entitled ''Medical Device Patient Labeling''. The purpose of the public workshop is to discuss issues associated with the development and use of medical device

patient labeling including content, testing, use, access, human factors, emerging media formats, and promotion and advertising. The Center for Devices and Radiological Health (CDRH) is seeking input into these topics from patients and advocacy groups, academic and professional organizations, industry, standards organizations, and governmental Agencies. Ideas generated during this workshop will help facilitate development or revision of guidances and/or standards for medical device patient labeling.

Date and Time: The workshop will be held on September 29, 2015, from 8 a.m. to 5 p.m. and September 30, 2015, from 8 a.m. to 5 p.m.

Location: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503A), Silver Spring, MD 20993–0002. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please visit the following Web site: *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm*

Contact Person: Antoinette (Tosia) Hazlett, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5424, Silver Spring, MD 20993–0002, 301–796–6119, *Tosia.Hazlett@fda.hhs gov*.

Registration: Registration is free and available on a first-come, first-served basis. Persons interested in attending the ''Medical Device Patient Labeling'' public workshop must register online by 4 p.m. on September 21, 2015. Early registration is recommended because facilities are limited and, therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the days of the public workshop will be provided beginning at 7 a.m. If you need special accommodations due to a disability, please contact Susan Monahan at least 7 days in advance of the meeting.

To register for the public workshop, please visit CDRH's Workshops and Conferences calendar at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm*. (Select this public workshop from the posted events list.) Please provide complete contact information for each attendee, including name, title, affiliation, email, and telephone number. Those without Internet access should contact Susan Monahan to register (see *Contact Person*). Registrants will receive confirmation after they have been accepted. You will be notified if you are on a waiting list.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by 4 p.m. on September 21, 2015. Early registration is recommended because Webcast connections are limited. Organizations are requested to register all participants, but to view using one connection per location. Webcast participants will be sent technical system requirements after registration and will be sent connection access information after September 25, 2015. If you have never attended a Connect Pro event before, test your connections at *https://collaboration.fda.gov/common/help/en/support/meeting_test.htm.* (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Comments: FDA is holding this public workshop to obtain stakeholder input on medical device patient labeling. In order to permit the widest possible opportunity to obtain public comment, FDA is soliciting either electronic or written comments on all aspects of the public workshop. The deadline for submitting comments regarding this public workshop is October 30, 2015.

Regardless of attendance at the public workshop, interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville MD 20852. 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. In addition, when responding to specific topics as outlined in ''Topics for Discussion'', please identify the topic you are addressing. 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.*

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at: *http://www.regulations.gov.* A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcripts will also be available approximately 45 days after the public workshop on the Internet at: *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.*

SUPPLEMENTARY INFORMATION:

I. Background

The CDRH Guidance on Medical Device Patient Labeling (available at *http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070782.htm*) serves to assist manufacturers in their development of patient labeling and to assist Center reviewers in their review and evaluation of the manufacturers' labeling. Medical device patient labeling includes any medical device information that is intended for a lay audience. It is intended to help assure that the device is used safely and effectively. This labeling may pertain to therapeutic, restorative, diagnostic, or cosmetic devices. Medical device patient labeling is supplied in many formats, for example: As patient brochures, patient leaflets, user manuals, videos or audio recording, and through physical or online media. This labeling is intended to be supplied to or available to patients or their lay caregivers for their use with or without accompanying professional counseling. While some patients receive labeling from their healthcare practitioners or device suppliers, others receive it in the packaging of over-the-counter devices. CDRH is collecting public comment to use in updating the Medical Device Patient Labeling Guidance.

FDA is committed to supporting the development and availability of patient labeling which supports the safe and effective use of medical devices by patients. To inform FDA in their efforts, they are seeking input on the topics identified in section II.

II. Topics for Discussion

FDA seeks to address and receive comments on the following topics:

A. Current Medical Device Patient Labeling

(1) The current use and practice trends of medical device patient labeling development and use. For example: When is medical device patient labeling used? How much medical device patient labeling exists? How much modification and revision of existing medical device patient labeling

occurs, and under what circumstances? What is the role of voluntary consensus standards in developing medical device patient labeling?

(2) What risks or adverse outcomes have been reported in association with the use of medical device patient labeling? What communication barriers have been encountered, and how can they be mitigated?

(3) Is there any part of the medical device patient labeling development process that presents a barrier to receiving approval or clearance from CDRH? If so, please provide examples of the specific issues, how frequently this occurs, and suggestions which constructively address these barriers.

(4) What are the best ways to foster efficient networking with patients and advocacy groups, academic and professional organizations, industry, standards organizations, and government Agencies to address medical device patient labeling needs?

B. Medical Device Patient Labeling Needs Assessment

(1) Describe the parameters that should be used in determining priority areas of development of medical device patient labeling, including both therapeutic and diagnostic devices.

(2) What are best practices for conducting a needs assessment of medical device patient labeling?

C. Advancing Development

(1) What could advance the development and use of medical device patient labeling?

(2) How should patient labeling be considered in the development stages of all medical device labeling?

(3) What resources (*e.g.,* registries, industry, or patient advocacy groups,) could be tapped to advance the development of medical device patient labeling?

(4) What are potential changes to guidances and regulations, or advances in current science that may help develop and enhance medical device patient labeling to address the needs of medical device manufacturers, device suppliers, and device users?

Dated: July 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17800 Filed 7–20–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0411]

Cooperative Agreement for Research, Education, and Outreach in Support of the Food and Drug Administration Food Safety Modernization Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of grant funds for a cooperative agreement to support the FDA Food Safety Modernization Act (FSMA) implementation efforts by the Illinois Institute of Technology's (IIT) National Center for Food Safety and Technology (NCFST). The estimated amount of support in fiscal year (FY) 2015 will be for up to $5 million (direct plus indirect costs), with the possibility of 2 additional years of support for up to $7 million each year, subject to the availability of funds. This award will improve public health by continued support of an applied research, education, and outreach program related to the science behind and implementation of preventive controls, and on training and technical assistance.

DATES: Important dates are as follows:

1. The application due date is August 14, 2015.
2. The anticipated start date is September 1, 2015.
3. The opening date is August 1, 2015.
4. The expiration date is August 31, 2015.

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

FOR FURTHER INFORMATION CONTACT: Wanda Honeyblue, Food and Drug Administration, Center for Food Safety and Applied Nutrition (CFSAN), 5100 Paint Branch Pkwy. (HFS–002), Rm. 4D–034, College Park, MD 20740, 301–796–3500, email: *wanda.honeyblue@fda.hhs.gov;* or Martin Bernard, Division of State Acquisitions, Agreements and Grants (DSAAG) (HFA–500), Food and Drug Administration, 5630 Fishers Lane, Rockville, MD 20857, 240–402–7564, email: *Martin.Bernard@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/.*

SUPPLEMENTARY INFORMATION:

I. Funding Opportunity Description

Funding Opportunity Number: RFA–FD–15–035

Catalog of Federal Domestic Assistance Number: 93.103

A. Background

FDA has supported the NCFST under seven previously awarded cooperative agreements (53 FR 15736, 56 FR 46189, 59 FR 24703, 64 FR 39512, 69 FR 25405, 74 FR 26408, and 79 FR 23360). NCFST was established by IIT to bring together the food safety and technology expertise of academia, industry, and FDA for the purpose of supporting research and outreach efforts related to the safety of foods based on a common goal of enhancing the safety of the food supply for U.S. consumers. NCFST has been successful in developing research programs such as those related to low-moisture foods, and outreach programs such as those related to sprout safety; these successes were achieved as a result of NCFST partnering with industry, academia, and FDA.

NCFST is structured so that representatives of participating organizations play a role in establishing policy and administrative procedures, as well as identifying long- and short-term research, outreach, and training needs. With this organizational structure, NCFST is able to build cooperative food safety programs on a foundation of knowledge about current industrial trends in food processing and packaging technologies, regulatory perspectives from public health organizations, and fundamental scientific expertise from academia. This award will improve public health by continued support of an applied research, education, and outreach program related to the science behind and implementation of preventive controls associated with manufacturing, processing, packing, and holding of human and animal food, and on training and technical assistance.

B. Program Objectives

With an increasingly diverse domestic and global food supply, FDA continues to face complex food safety issues associated with the foods that it regulates. Some of these complex issues can be effectively addressed by further strengthening the available science-based programs established through NCFST/Institute for Food Safety and Health (IFSH). FDA also believes that innovative research and outreach programs such as those established at NCFST/IFSH can further support the development of proactive approaches to