reporting systems. The expert panel of judges, qualified by training and experience, will evaluate the submissions on the criteria identified below in this section. Judges will be fair and impartial, may not have a personal or financial interest in, or be an employee, officer, director, or agent of, any entity that is a registered participant in the competition, and may not have a personal or financial relationship with an individual who is a registered contestant. The panel will provide expert advice on the merits of each submission to CMS officials responsible for final selections for award. Awardees will be notified on or around the dates listed in the ''Date'' section. Winners will be selected based on the following criteria:

- Phase 1

++ Ease in which a user can navigate Usability and Design;

++ Evidence of design with User feedback;

++ Innovation in Design; and

++ Look and Feel.

- Phase 2

++ Ease in which a user can navigate Usability and Design;

++ Evidence of design with User feedback;

++ Innovation in Design;

++ Functionality/Accuracy; and

++ Look and Feel.

C. Additional Information

Challenge participants will draw from existing information provided on *www.cms.gov* and collaborate directly with health professionals and/or end users to build their application. The participants will have access to *www.cms.gov* and to end users. Challenge details and registration are located at *www.challenge.gov.*

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: June 29, 2016.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2016–16808 Filed 7–14–16; 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; Refugee Microenterprise and Refugee Home-Based Child Care Microenterprise Development

OMB No.: New.

Description: New data collection tool for refugee microenterprise and Refugee Home-Based Child Care Microenterprise Program.

Respondents: Refugee Microenterprise Development Grantees and Refugee Home-Based Child Care Microenterprise Development.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Microenterprise Development	22	8	4	704
Refugee Home-Based Child Care Microenterprise Development	23	7	4	644
Total Burden				1,348

Estimated Total Annual Burden Hours: (1,340 hours × $30 per hour) $40,440 per year.

Explanation:

The Refugee Microenterprise Development Program

- Currently, there are twenty two grantees (respondents) in the program and the semi-annual progress, which includes the data and information required, is submitted twice per year.
- The request covers one form (Form I. attached) which includes eight data points. Based on experience (the information was provided by technical assistance service provider in the past), it takes about two hours per respondent per six months (*i.e.,* four hours per year per grantee (respondent) or 88 hours per year for all respondents) to complete the form.
- No survey will be undertaken since the collection of this data (information) is part of the implementation process of the project and its collection and reporting does not constitute a separate and additional cost to the grantees (respondents). The cost is covered by the grant the grantee receives. The grantees have Down Home database which captures and stores the data required for reporting. The grantee uploads the semi-annual report in Grant Solution where it is stored. ORR derives the data it requires for reporting and management decision from Grant Solution.

The Refugee Home-Based Child Care Microenterprise Development Group

- Currently, there are twenty three grantees (respondents) in the program and the semi-annual progress.
- The request covers one form (Form II. attached) which includes seven data points. It takes about two hours per respondent per six months (*i.e.,* four hours per year grantee (respondent) or 92 hours per year for all respondents) to complete the form.
- The collection of this data (information) is part of the process and its collection and reporting does not include separate and additional cost to the grantees (respondents). The cost is covered by the grant the grantee receives. The grantees have database which captures and stores the data required for reporting. The grantee uploads the data required in Grant Solution where it is stored. ORR derives the data it requires for reporting and management decision from Grant Solution.

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. 2016–16700 Filed 7–14–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund (CCDF) Tribal Reporting Requirements—ACF–700.

OMB No.: 0970–0430.

Description: The Child Care and Development Fund (CCDF) Tribal Annual Report (ACF–700) requests annual Tribal aggregate information on services provided through the CCDF, which is required by CCDF regulations (45 CFR parts 98 and 99). Tribal Lead Agencies (TLAs) are required to submit annual aggregate data appropriate to Tribal programs on children and families receiving CCDF-funded child care services. The revised ACF–700 report consists of two parts: (1) Administrative Data, and (2) Tribal Narrative. The content and format of the narrative section have been revised to make the form easier to complete with new check box formatting. These revisions will allow the Office of Child Care (OCC) to more easily generate and quantify data in the report. These changes will help us better understand Tribal activities as they relate to compliance, quality of child care, use of funds, and technical assistance needs. Information from the ACF–700 will be included in the Secretary's Report to Congress, as appropriate, and will be shared with all TLAs to inform them of CCDF-funded activities in other Tribal programs. CCDF-funded Tribes that receive their funds under Public Law 102–477 are not required to submit the ACF–700.

Respondents: Tribal Governments.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–700 Report	260	1	38	9,880

Estimated Total Annual Burden Hours: 9,880.

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, 330 C Street SW., Washington, DC 20201. Attention 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. 2016–16697 Filed 7–14–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–1703]

Principles for Codevelopment of an In Vitro Companion Diagnostic Device With a Therapeutic Product; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Principles for Codevelopment of an In Vitro Companion Diagnostic Device with a Therapeutic Product.'' This draft guidance is intended to be a practical guide to assist therapeutic product sponsors and in vitro diagnostic device (IVD) sponsors in developing a therapeutic product with an accompanying IVD companion diagnostic, a process referred to as codevelopment. This draft guidance is also intended to assist FDA staff participating in the review of such IVD companion diagnostics or their associated therapeutic products. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 13, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that