

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]

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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.

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Robert Sargis,

Reports Clearance Officer.

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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