submissions to Congress. Financial management of the program would be seriously compromised if the expenditure data were not collected.

45 CFR part 286 Subpart E requires the strictest controls on funding requirements, which necessities review of documentation in support of Tribal expenditures for reimbursement.

Comments received from previous efforts to implement a similar Tribal TANF report Form ACF–196T were used to guide ACF in the development of the product presented with this submittal.

Respondents: All approved Tribal TANF Agencies. Those with consolidated Tribal TANF programs plans under 102–477 may submit the Tribal TANF Financial Report to BIA with a copy to: ACF Division of Mandatory Grants, 330 C Street SW., Washington, DC 20201. Or at their convenience may elect to use the On-Line Data Collection System to electronically submit their quarterly Tribal TANF Financial Report.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–196T	72	4	1.25	360

Estimated Total Annual Burden Hours: 360.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–09123 Filed 4–19–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Form ACF–696T, ''Child Care and Development Fund Annual Financial Report for Tribes''

OMB No.: 0970–0195.

Description: This form is used by Tribes and Tribal Organizations that have been approved as grantees to administer the Child Care and Development Fund program (CCDF). This form is submitted annually to report CCDF program expenditures to the Administration for Children and Families.

The authority to collect and report this information can be found in Section 658G of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101–508), as amended, and in Federal regulations at 45 CFR 98.65(g) and 98.67(c)(1) which authorize the Secretary to require financial reports as necessary.

Respondents: Tribes and Tribal Organizations.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Form ACF–696T, ''Child Care and Development Fund Annual Financial Report for Tribes''	272	1	6	1,632

Estimated Total Annual Burden Hours: 1,632.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington DC 20201. Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the

agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2016–09055 Filed 4–19–16; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–0973]

Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information.'' This document is a revised version of a draft guidance that published in February 2003 entitled ''Comparability Protocols: Chemistry, Manufacturing, and Controls Information.'' A related draft guidance entitled ''Comparability Protocols—Protein Drug Products and Biological Products—Chemistry, Manufacturing, and Controls Information,'' that published in September 2003, was withdrawn on May 6, 2015.

The revised draft guidance provides recommendations to human drug and biologics manufacturers on implementing a chemistry, manufacturing, and controls (CMC) postapproval change(s) through the use of a comparability protocol (CP). By using a CP, manufacturers who fall within the scope of this guidance will not have to submit commercial-scale CMC information on postchange products to FDA before making the proposed change. This draft guidance is intended to establish a framework to promote manufacturing of quality drug products.

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 on 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 June 20, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Comments

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 identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–D–0973 for ''Comparability Protocols for Human Drugs and Biologics: Chemistry, Manufacturing, and Controls Information.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Stephen Moore, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 21, Rm. 2012, 10903 New Hampshire Ave.,