valid authorization. In order to be valid, an authorization must include specified core elements and statements. CMS will make available to PCIP applicants and enrollees a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. CMS will make available to PCIP applicants and enrollees a standard, valid authorization to enable beneficiaries to communicate with PCIP about their personal health information. This is a critical tool because the population the PCIP program serves is comprised of individuals with pre-existing conditions who may be incapacitated and need an advocate to help them apply for or receive benefits from the program. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for the PCIP program; *Form Number:* CMS–10428 (OMB 0938–New); *Frequency:* Occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 2,100; *Total Annual Responses:* 2,100; *Total Annual Hours:* 525. (For policy questions regarding this collection contact Laura Dash at 410–786–8623. For all other issues call 410–786–1326.)

CMS is requesting OMB review and approval of this collection by March 22, 2012. To be assured consideration, comments and recommendations for the proposed information collections must be received by via one of the methods below on March 19, 2012.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web Site address at *http://www.cms.gov/PaperworkReductionActof1995/PRAL/list.asp* or Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*, or call the Reports Clearance Office on (410) 786–1326.

Interested persons are invited to send comments regarding the burden or any other aspect of these collections of information requirements. However, as noted above, comments on these information collection and recordkeeping requirements must be received via one of the following methods by March 19, 2012.

1. *Electronically.* You may submit your comments electronically to *http://www.regulations.gov.* Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier CMS–10417, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

3. *By Email to OMB.* OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Email: OIRA_submission@omb.eop.gov.*

Dated: March 8, 2012.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2012–6035 Filed 3–12–12; 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: Descriptive Study of Tribal Temporary Assistance for Needy Families (TANF) Programs—Interview Guides.

OMB No.: New Collection.

Description: The Administration for Children and Families (ACF) is proposing an information collection activity as part of the Descriptive Study of Tribal TANF Programs. The proposed information collection consists of semi-structured interviews and focus groups with key Tribal TANF respondents on questions of Tribal TANF administration, policies, service delivery, and program context. Through this information collection, ACF seeks to gain an in-depth, systematic understanding of program implementation, operations, outputs and outcomes in selected sites, and identify promising practices and other areas for further study.

Respondents: Semi-structured interviews will be held with Tribal TANF administrators and staff, and staff of related programs. Focus groups will be held with Tribal TANF clients.

Annual Burden Estimates

Please note that the burden rates below are revised since the 60 day **Federal Register** Notice to reflect lower burden hours.

TABLE 1—ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Discussion Guide for use with tribal TANF Administrators	4	1	1.5	6
Discussion Guide for use with tribal TANF Staff	12	1	1	12
Discussion Guide for use with Focus Groups with tribal TANF clients	20	1	2	40
Discussion guide for use with staff of related programs	20	1	1	20
All instruments:				78

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@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, Fax: 202–395–6974, Attn: Desk Officer for the Administration for Children and Families.

Dated: March 7, 2012.

Steven M. Hanmer,

Reports Clearance, Officer; Office of Planning, Research and Evaluation.

[FR Doc. 2012–5951 Filed 3–12–12; 8:45 am]

BILLING CODE 4184–37–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0194]

Agency Information Collection Activities: Proposed Collection; Comment Request; Biosimilars User Fee Cover Sheet; Form FDA 3792

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments concerning Form FDA 3792, entitled ''Biosimilars User Fee Cover Sheet.''

DATES: Submit written or electronic comments on the collection of information by May 14, 2012.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *Juanmanuel.vilela@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60 day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques when appropriate, and other forms of information technology.

The March 23, 2010 Affordable Care Act contains a subtitle called the Biologics Price Competition and Innovation Act of 2009 (BPCI Act) that amends the Public Health Service Act (PHS Act) and other statutes to create an abbreviated approval pathway for biological products shown to be biosimilar to or interchangeable with an FDA-licensed reference biological product. Section 351(k) of the PHS Act, added by the BPCI Act, allows a company to submit an application for licensure of a biosimilar or interchangeable biological product. The BPCI Act also amends section 735 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include 351(k) applications in the definition of ''human drug application'' for the purposes of the prescription drug user fee provisions. The authority conferred by the FD&C Act's prescription drug user fee provisions expires in September, 2012. The BPCI Act directs FDA to develop recommendations for a biosimilar biological product user fee program for fiscal years 2013 through 2017. FDA's recommendations for a biosimilar biological product user fee program were submitted to Congress on January 13, 2012. If enacted into law, FDA's proposed biosimilar biological product user fee program would require FDA to assess and collect user fees for certain meetings concerning biosimilar biological product development (BPD meetings), investigational new drug applications (INDs) intended to support a biosimilar biological product application, and biosimilar biological product applications and supplements. Proposed Form FDA 3792, the Biosimilars User Fee Cover Sheet, requests the minimum necessary information to determine the amount of the fee required, and to account for and track user fees. The form would provide a cross-reference of the fees submitted for a submission with the actual submission by using a unique number tracking system. The information collected would be used by FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research to initiate the administrative screening of biosimilar biological product INDs, applications, and supplements, and to account for and track user fees associated with BPD meetings.

Respondents to this proposed collection of information would be manufacturers of biosimilar biological product candidates. Based on FDA's database system, there are an estimated 18 manufacturers that fall into this category. However, not all manufacturers will have submissions in a given year and some may have multiple submissions. FDA estimates nine annual responses that include the following: Six INDs or BPD meetings, two applications, and one supplement. The estimated hours per response are based on FDA's past experience with other submissions, and average 30 minutes.