

**Kimberly S. Lane,**  
*Deputy Director, Office of Scientific Integrity,  
 Office of the Associate Director for Science,  
 Office of the Director, Centers for Disease  
 Control and Prevention.*  
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**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Administration for Children and  
 Families**

**Submission for OMB Review;  
 Comment Request**

*Title:* Tribal TANF Data Report, TANF  
 Annual Report, and Reasonable Cause/

Corrective Action Documentation  
 Process—Final.  
*OMB No.:* 0970-0215.  
*Description:* 42 U.S.C. 612 (Section  
 412 of the Social Security Act as  
 amended by Pub. L. 104-193, the  
 Personal Responsibility and Work  
 Opportunity Reconciliation Act of 1996  
 (PRWORA)), mandates that federally  
 recognized Indian Tribes with an  
 approved Tribal TANF program collect  
 and submit to the Secretary of the  
 Department of Health and Human  
 Services data on the recipients served  
 by the Tribes' programs. This  
 information includes both aggregated  
 and disaggregated data on case  
 characteristics and individual  
 characteristics. In addition, Tribes that

are subject to a penalty are allowed to  
 provide reasonable cause justifications  
 as to why a penalty should not be  
 imposed or may develop and implement  
 corrective compliance procedures to  
 eliminate the source of the penalty.  
 Finally, there is an annual report, which  
 requires the Tribes to describe program  
 characteristics. All of the above  
 requirements are currently approved by  
 OMB and the Administration for  
 Children and Families is simply  
 proposing to extend them without any  
 changes.

*Respondents:* Indian Tribes.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Final Tribal TANF Data Report .....	66	4	451	119,064
Tribal TANF Annual Report .....	66	1	40	2,640
Tribal TANF Reasonable Cause/Corrective .....	66	1	60	3,960

*Estimated Total Annual Burden  
 Hours:* 125,664.

*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, Fax: 202-395-7285,  
 Email:  
*OIRA\_SUBMISSION@OMB.EOP.GOV.*  
 Attn: Desk Officer for the

Administration for Children and  
 Families.

**Robert Sargis,**  
*Reports Clearance Officer.*  
 [FR Doc. 2012-13630 Filed 6-5-12; 8:45 am]  
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**DEPARTMENT OF HEALTH AND  
 HUMAN SERVICES**

**Administration for Children and  
 Families**

**Submission for OMB Review;  
 Comment Request**

Proposed Projects:  
*Title:* Performance Measures for  
 Community-Centered Healthy Marriage,  
 Pathways to Responsible Fatherhood  
 and Community-Centered Responsible  
 Fatherhood Ex-Prisoner Reentry Grant  
 Programs.  
*OMB No.:* 0970-0365.  
*Description:* The Office of Family  
 Assistance (OFA), Administration for  
 Children and Families (ACF), U.S.  
 Department of Health and Human  
 Services (HHS), intends to request  
 approval from the Office of Management  
 and Budget (OMB) to renew OMB Form  
 0970-0365 for the collection of  
 performance measures from grantees for  
 the Community-Centered Healthy

Marriage, Pathways to Responsible  
 Fatherhood and Community-Centered  
 Responsible Fatherhood Ex-Prisoner  
 Reentry discretionary grant programs.  
 The performance measure data obtained  
 from the grantees will be used by OFA  
 to report on the overall performance of  
 these grant programs. Data will be  
 collected from all 61 Community-  
 Centered Healthy Marriage, 53 Pathways  
 to Responsible Fatherhood and 4  
 Community-Centered Responsible  
 Fatherhood Ex-Prisoner Reentry  
 grantees in the OFA programs. Grantees  
 will report on program and participant  
 outcomes in such areas as participants'  
 improvement in knowledge skills,  
 attitudes, and behaviors related to  
 healthy marriage and responsible  
 fatherhood. Grantees will be asked to  
 input data for selected outcomes for  
 activities funded under the grants.  
 Grantees will extract data from program  
 records and will report the data twice  
 yearly through an on-line data  
 collection tool. Training and assistance  
 will be provided to grantees to support  
 this data collection process.

*Respondents:* Office of Family  
 Assistance Funded Community-  
 Centered Healthy Marriage, Pathways to  
 Responsible Fatherhood and  
 Community-Centered Responsible  
 Fatherhood Ex-Prisoner Reentry  
 Grantees.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Performance measure reporting form (for private sector affected public) .....	103	2	0.8	165
Performance measure reporting form (for State, local, and tribal government affected public) .....	15	2	0.8	24
Estimated Total Annual Burden Hours .....				189

*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](mailto: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, Fax: 202-395-7285, Email: [OIRA\\_SUBMISSION@OMB.EOP.GOV](mailto:OIRA_SUBMISSION@OMB.EOP.GOV), Attn: Desk Officer for the Administration for Children and Families.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2012-N-0536]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Device User Fee Cover Sheet, Form FDA 3601

**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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3601, entitled "Medical Device User Fee Cover Sheet," which must be submitted along with certain medical device product applications, supplements, and fee payment of those applications.

**DATES:** Submit either electronic or written comments on the collection of information by August 6, 2012.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information 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:**

Daniel Gittleston, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, [Daniel.Gittleston@fda.hhs.gov](mailto:Daniel.Gittleston@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, including each proposed extension of an existing 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 these topics: (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.

#### Medical Device User Fee Cover Sheet—Form FDA 3601 (OMB Control Number 0910-0511)—Extension

The Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (Pub. L. 107-250), and the Medical Device User Fee Amendments of 2007 (Title II of the Food and Drug Administration Amendments Act of 2007), authorizes FDA to collect user fees for certain medical device applications. Under this authority, companies pay a fee for certain new medical device applications or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, the review of an application cannot begin until the fee is submitted. Form FDA 3601, the "Medical Device User Fee Cover Sheet," is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees.

The form provides a cross-reference between the fees submitted for an application with the actual submitted application by using a unique number