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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.

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. 2012-13602 Filed 6-5-12; 8:45 am]

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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 Gittleson, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-5156, Daniel.Gittleson@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