

Selective settings (*i.e.*, venues selected in which we have or can establish relationships with organizations that can identify and encourage participation by low-income couples/parents) in

order to gain information and insights early in the project development period; and (2) site-specific settings, after programs become part of the formal study, to help inform site-specific

program designs to address needs among the target population. The selective settings will be the focus of the first round of information collection.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Focus Group Protocol .....	144	1	1.5	216
Information Sheet .....	144	1	.10	14.4
Estimated Total Annual Burden Hours .....				230.4

In compliance with the requirements of section 3506(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 Information Services, 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.

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.

Dated: February 10, 2003.

**Bob Sargis,**

*Reports Clearance Officer.*

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Administration for Children and Families

##### Proposed Information Collection Activity; Comment Request

*Proposed Project:* Collection of data on American Indian and Alaska Native

needy families receiving temporary assistance from programs operated by American Indian and Alaska Native entities (Indian tribes).

*Title:* Tribal Temporary Assistance For Needy Families Program (Tribal TANF) Data Reporting Instructions and Requirements.

*OMB No:* 0970-0215.

*Description:* 42 U.S.C. 612 (section 412 of the Social Security Act—the 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 (HHS) data on the recipients served by their programs. Instructions and requirements for submitting that data are the subject of this request for comments.

*Respondents:* Indian tribes that have an approved tribal TANF program.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Tribal TANF Data reports .....	56	24	50	67,200
Estimated Total Burden: .....				67,200

In compliance with the requirements of section 3506(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 Administration, Office of Information Services, 370

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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.

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 03N-0034]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; FDA Safety Alert/Public Health Advisory Readership Survey

**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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for the FDA Safety Alert/Public Health Advisory Readership Survey.

**DATES:** Submit written or electronic comments on the collection of information by April 21, 2003.

**ADDRESSES:** Submit electronic comments on the collection of information to <http://www.accessdata.fda.gov/scripts/oc/dockets/edockethome.cfm>. Submit written comments on the collection of information to the Dockets Management Branch (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:

Peggy Robbins, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

**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 listed below.

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.

#### FDA Safety Alert/Public Health Advisory Readership Survey (OMB Control No. 0910-0341)—Extension

Section 705(b) (21 U.S.C. 375(b)) of the Federal Food, Drug, and Cosmetic Act (the act) authorizes FDA to disseminate information concerning imminent danger to public health by any regulated product. The Center for Devices and Radiological Health (CDRH) communicates these risks to user communities through two publications: (1) The FDA Safety Alert and (2) the Public Health Advisory. Safety alerts and advisories are sent to organizations such as hospitals, nursing homes, hospices, home health care agencies, manufacturers, retail pharmacies, and other health care providers. Subjects of previous alerts included spontaneous combustion risks in large quantities of patient examination gloves, hazards associated with the use of electric heating pads, and retinal photic injuries from operating microscopes during cataract surgery.

Section 1701(a)(4) (42 U.S.C. 300u(a)(4)) of the Public Health Service Act authorizes FDA to conduct research relating to health information. FDA seeks to evaluate the clarity, timeliness, and impact of safety alerts and public health advisories by surveying a sample of recipients. Subjects will receive a questionnaire to be completed and returned to FDA. The information to be collected will address how clearly actions for reducing risk are explained, the timeliness of the information, and whether the reader has taken any action to eliminate or reduce risk as a result of information in the alert. Subjects will also be asked whether they wish to receive future alerts electronically, as well as how the safety alert program might be improved.

The information collected will be used to shape FDA's editorial policy for the safety alerts and public health advisories. Understanding how target audiences view these publications will aid in deciding what changes should be considered in their content, format, and method of dissemination.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
308	3	924	.17	157

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on the history of the safety alert and public health advisory program, it is estimated that an average of three collections will be conducted a year.

The total burden of response time is estimated at 10 minutes per survey. This was derived by CDRH staff completing

the survey and through discussions with the contacts in trade organizations.