

assess the quality of survey data and attrition.

*Respondents:* The target population of the SHM study is low-income married couples with children or expecting a child. Both members of the couple must be over 18, and both must volunteer to participate in the program. In addition, SHM is not intended for couples who are in dangerous relationships or who are experiencing serious family violence. Programs will provide opportunities for the safe disclosure of

family violence, as well as access to appropriate services when family violence is disclosed.

The respondents for the Supporting Healthy Marriage Project Baseline Data Collection will be participants in the SHM study. This will include both those receiving SHM program services and those in the SHM study control group. The respondents will be both spouses of 1,000 low-income married couples (2,000 respondents) in each of up to eight sites. The total number of

respondents could be up to 16,000. In summary, the evaluation will include up to 8 sites phased in over four years, in which case the annual burden can be represented by one quarter of the total burden. The chart below outlines the estimated annual burden that could result from the SHM baseline data collection. The estimates below are based on pre-tests of the baseline instrument with individuals similar to the SHM target population.

**ANNUAL BURDEN ESTIMATES**

Instrument	Annual number of respondents	Number of responses per respondent	Average burden per response (min)	Estimated annual burden hours
Eligibility Checklist .....	4,000	1	5	332
Informed Consent Form .....	4,000	1	10	668
Baseline Information Form .....	4,000	1	9	600
Self-Administered Questionnaire .....	4,000	1	11	732
Contact Information Sheet .....	4,000	1	10	668

*Estimated Annual Burden Hours:* 3,000.

*Additional Information:* Copies of the proposed collection may be obtained 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. E-mail address: [infocollections@acf.hhs.gov](mailto:infocollections@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, Attn: Desk Officer for

ACF, E-mail address: [Katherine.T.Astrich@omb.eop.gov](mailto:Katherine.T.Astrich@omb.eop.gov).

Dated: March 31, 2006.

**Robert Sargis,**  
*Reports Clearance Officer.*  
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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

[OMB No. 0970-0174]

**Proposed Information Collection Activity; Comment Request**

**Proposed Projects**

*Title:* Native Employment Works (NEW) Program Plan Guidance and Program Report

*Description:* The Native Employment Works (NEW) program plan is the application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance specifies the information needed to complete a NEW program plan and explains the process for plan submission every third year. The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

*Respondents:* Federally recognized Indian Tribes and Tribal organizations that are NEW program grantees.

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
NEW program plan guidance .....	26	1 every 3 years .....	29	754
NEW program report .....	48	1 annually .....	15	720

Estimated Total Annual Burden Hours: 1,474

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 L'Enfant Promenade, SW., Washington,

DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [infocollection@acf.hhs.gov](mailto: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.

Dated: March 31, 2006.

**Robert Sargis,**

*Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N-0457]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Substances Generally Recognized as Safe: Notification Procedure

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by May 8, 2006.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Jonna Capezzuto, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4659.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

#### Substances Generally Recognized as Safe: Notification Procedure (OMB Control Number 0910-0342)—Extension

Section 409 of the act (21 U.S.C. 348) establishes a premarket approval requirement for "food additives;" section 201(s) of the act (21 U.S.C. 321(s)) provides an exemption from the definition of "food additive" and thus from the premarket approval requirement, for uses of substances that are generally recognized as safe (GRAS) by qualified experts. FDA is proposing a voluntary procedure whereby members of the food industry who determine that use of a substance satisfies the statutory exemption may notify FDA of that determination. The notice would include a detailed summary of the data and information that support the GRAS determination, and the notifier would maintain a record of such data and information. FDA would make the information describing the GRAS claim, and the agency's response to the notice, available in a publicly accessible file; the entire GRAS notice would be publicly available consistent with the Freedom of Information Act (FOIA) and other Federal disclosure statutes.

In the **Federal Register** of December 8, 2005 (70 FR 73009), FDA published a 60-day notice requesting public comment on the information collection provisions to which one comment was received. The comment states that obtaining the entire GRAS notification through the provisions of FOIA is not a practical means for interested persons to learn about the safety of a substance. The comment suggests that, to enhance the quality, utility, and clarity of the information to be collected, FDA should make publicly available a summary of data and information that supports the GRAS notice and also contains a discussion of any negative or inconsistent data.

FDA does not agree that obtaining information through the provisions of

FOIA is impractical for interested persons. FDA also disagrees with the comment's suggestion that the agency make publicly available in the GRAS notification process a summary of data and information that supports the GRAS notice and also contains a discussion of any negative or inconsistent data, because such a summary would be duplicative of information available through FOIA procedures. This information collection is associated with the proposed rule entitled "Notice of a Claim for GRAS Exemption Based on a GRAS Determination" (the proposed rule) (62 FR 18938). Proposed § 170.36(c)(4) describes requirements for a detailed summary in the GRAS notification procedures. This section states that notifiers shall submit a detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the act because such use is GRAS. Such determination may be based either on scientific procedures or on common use in food. Proposed § 170.36(c)(4)(i)(B) and 170.36(c)(4)(ii)(B) state that this detailed summary shall contain a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination. Proposed § 170.36(f)(1) states that all remaining data and information in the GRAS notice shall be available for public disclosure, in accordance with the provisions of FOIA, on the date the notice is received. This would include the detailed summary of the basis for the notifier's GRAS determination. To the extent that the comment suggests a change to the requirements of the proposed rule, FDA responds that such a request is outside the scope of the four collection of information topics on which the notice solicits comments and, thus, will not be addressed in this document. In response to the request for comments in that proposed rule, the commenter timely filed a similar comment. This comment will be considered in the development of the final rule.

*Description of Respondents:* Manufacturers of Substances Used in Food and Feed.

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