DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Building Strong Families (BSF) Demonstration and Evaluation—Impact Study Second Follow-up.

OMB No.: 0970–0304.

Description: The Administration for Children and Families (ACF), U.S.Department of Health and Human Services (HHS), anticipates continuing data collection for the 15-month follow-up surveys of the Building Strong Families (BSF) Demonstration and Evaluation. Data collection will continue for an additional 6 months beyond the current date of expiration (July 31, 2009).

This data collection is a part of the BSF evaluation, which is an important opportunity to learn if well-designed interventions can help low-income couples develop the knowledge and relationship skills that research has shown are associated with healthy marriages. The BSF evaluation uses an experimental design that randomly assigns couples who volunteer to participate in BSF programs to a program or control group.

Materials for the original 15-month data collection effort, previously submitted to OMB, covered impact and implementation data collections. Data collection for the impact study is complete. ACF anticipates collecting data for an additional 6 months in order to complete data collection for the entire sample of participants.

Respondents: Couples enrolled in the BSF evaluation, including program and control groups.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
15-month telephone survey (female partner)	1,434	1	.91	1,305
15-month telephone survey (male partner)	1,434	1	.83	1,190

Total Burden Hours: 2,495

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research andEvaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: OPREReports Clearance Officer. All requests should be identified by the title of the information collection. *E-mail 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 **FederalRegister**. 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: February 6, 2009.

Brendan C. Kelly,

Clearance Officer.

[FR Doc. E9–3053 Filed 2–13–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects:

Title: Grant Application Data Summary (GADS) Form.

OMB No.: 0970–0328.

Description: The purpose of this request is to obtain emergency OMB clearance of the Grant Application Data Summary (GADS) form so information collected from all FY09 ANA grant applicants (in March 2009) is accurate.

The GADS collects information from applicants seeking grants from the Administration for Native Americans (ANA). ANA awards annual grants in nine competitive areas. Previously, ANA collected information using the GADS form for 4 competitive areas, not 9. The GADS form, which is part of the ANA discretionary grant application package, has been revised to comply with required changes made to the ANA FY09 Program Announcements (PAs). The PAs were changed to comply with a new policy established by ACF requiring that subcategories within a PA be broken down into a stand-alone PA. On 12/5/08, ANA published nine PAs to support this new requirement for separate PAs, it was necessary for ANA to change the GADS form to reflect the new PAs. Below are the changes to the GADS form: (please select relevant topic under one heading)

(1) Special Initiative: Family Preservation: Improving the Well-Being of Children Planning

Curriculum Development; Community Assessment; Develop a Family Preservation Strategic Plan

Please choose all relevant topics from the selection below:

Relationship and Marriage Education for Adults; Relationship and Marriage Education for Youth; Marriage Enrichment activities and services; Pre-marital education and marriage skills; Relationships Skills; Responsible Fatherhood or Parenting; Family preservation activities offered in a culturally appropriate and traditional manner; Absentee parent services, education and activities; Reduce child/infant abuse and neglect and family domestic violence; Needs of grandparents raising grandchildren; Foster Parent Training Family strengthening services to individuals with substance abuse issues; Public Advertising Campaigns; Research

(2) Special Initiative: Family Preservation: Improving the Well-Being of Children Implementation

Relationship & Marriage Education for Adults; Relationship & Marriage Education for Youth; Marriage Enrichment activities & services; Pre-marital education & marriage skills; Relationships Skills; Responsible Fatherhood; Parenting; Family preservation activities in a culturally appropriate & traditional manner; Absentee parent services, education & activities; Family Domestic Violence;

Grandparents raising grandchildren; Foster Parent Training; Family strengthening services to individuals with substance abuse issues; Public Advertising Campaigns; Research

(3) Native Language Preservation & Maintenance Assessment

Data Collection; Formal Language Assessment; Informal Language Assessment

(4) Native Language Preservation & Maintenance Planning

Plan & design Master/Apprentice programs; Plan & design comprehensive Native language immersion programs for a language nest or survival school; Plan, design & test curriculum for students, parents & language instructors; Plan & design teaching materials; Record, transcribe & archive oral testimony; Plan & design language resource materials using recorded oral testimony; Plan & design multi-media language learning tools; Plan & design teacher certification programs; Train teachers, interpreters or translators of Native languages

(5) Native Language Preservation & Maintenance Implementation

Produce/disseminate culturally relevant printed stories for children using the Native language of the community; Facilitate/encourage intergenerational teaching of Native American language skills; Disseminate culturally relevant materials to teach & enhance the use of Native American languages; Implement an immersion, mentor or distance learning model; Produce, distribute or participate in various media forms to broadcast Native languages; Implement an educational site-based immersion project

(6) Native Language Preservation & Maintenance ImmersionLanguage Nest; Language Survival School

Respondents: Federally Recognized Indian Tribes, Tribal Governments, Native American Non-profits, Tribal Colleges and Universities

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Grant Application Data Summary (GADS)	500	1	0.50	250

Estimated Total Annual Burden Hours: 250.

In compliance with the requirements of Section 506(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*. 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 11, 2009.

Janean Chambers,

Reports Clearance Officer.

[FR Doc. E9–3240 Filed 2–13–09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0006]

International Conference on Harmonisation; Draft Guidance on S9 Nonclinical Evaluation for Anticancer Pharmaceuticals; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''S9 Nonclinical Evaluation for Anticancer Pharmaceuticals.'' The draft guidance was prepared under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The draft guidance provides recommendations for nonclinical studies for the development of pharmaceuticals, including both drugs and biotechnology-derived products, intended to treat patients with advanced cancer. The recommendations describe the type and timing of nonclinical studies to support an investigational new drug application (IND) and the submission of a new drug application (NDA) or biologics license application (BLA). The draft guidance is intended to provide information on internationally accepted recommendations for nonclinical studies to facilitate the development of anticancer pharmaceuticals.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by April 20, 2009.

ADDRESSES: Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send two self-addressed adhesive labels to