

with project staff and marriage education service providers in the community will provide a detailed understanding of the administration and operation of the demonstrations. Focus group discussions will provide insights into participants' perspectives on marriage education and their experiences with the CHMI interventions.

In addition to the implementation information collected under this

request, an impact evaluation will be integrated with the implementation study and will assess the effects of healthy marriage initiatives by comparing family and child well-being outcomes in the CHMI communities with similar outcomes in comparison communities that are well-matched to the project sites. Data from the implementation studies will provide the basis for the instrumental variable

models of CHMI impacts to help determine direct or indirect exposure to marriage-related services. Baseline data collected under the impact evaluation has been approved by OMB (i.e., Control No. 0970-0322).

*Respondents:* Lead Project Staff; Service Provider Organization Staff; Key Community, Civic Stakeholders; and Program Participants.

#### ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Average number of responses per respondent	Average burden hours per response	Total burden hours
Administrative Interviews .....	200	2	1	400
Small Group Interviews .....	25	1	1.6	40
Estimated Total Annual Burden Hours .....				440

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [OPREinfo@acf.hhs.gov](mailto:OPREinfo@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, 2008.

**Brendan C. Kelly,**

*OPRE 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

*Title:* Generic Clearance to Conduct Qualitative Data Collections.

*OMB No.:* New Collection.

*Description:* The Office of Planning, Research and Evaluation (OPRE), 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) for a generic clearance that will allow OPRE to conduct a variety of qualitative data collections. Over the next three years, OPRE anticipates undertaking a variety of new research

projects in the fields of cash welfare, employment and self-sufficiency, Head Start, child care, healthy marriage and responsible fatherhood, and child welfare. In order to inform the development of OPRE research, to maintain a research agenda that is rigorous and relevant, and to ensure that research products are as current as possible, OPRE will engage in a variety of qualitative data collections in concert with researchers and practitioners throughout the field. OPRE envisions using a variety of techniques including semi-structured discussions, focus groups, telephone interviews, and in-person observations and site visits, in order to integrate the perspectives of program operators, policy officials and members of the research community.

Following standard OMB requirements, OPRE will submit a change request to OMB individually for every group of data collection activities undertaken under this generic clearance. OPRE will provide OMB with a copy of the individual instruments or questionnaires (if one is used), as well as other materials describing the project.

*Respondents:* Administrators or staff of State and local agencies or programs in the relevant fields; academic researchers; and policymakers at various levels of government.

## ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Semi-Structured Discussion and Information-Gathering Protocol .....	600	1	.5	300
Estimated Total Annual Burden Hours .....	.....	.....	.....	300

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 Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. E-mail address: [OPREinfocollection@acf.hhs.gov](mailto:OPREinfocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

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Dated: March 31, 2008.

**Brendan C. Kelly,**

*OPRE Reports Clearance Officer.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-N-0172]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Use

**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 the reporting and recordkeeping requirements for "New Animal Drugs for Investigational Use."

**DATES:** Submit written or electronic comments on the collection of information by June 9, 2008.

**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:** Denver Presley, Jr., Office of the Chief Information Officer (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**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.

#### **New Animal Drugs for Investigational Use—21 CFR Part 511 (OMB Control Number 0910-0117)—Extension**

FDA has authority under the Federal Food, Drug, and Cosmetic Act (the act) to approve new animal drugs. Section 512(j) of the act (21 U.S.C. 360b(j)), authorized FDA to issue regulations for the investigational use of new animal drugs. The regulations which set forth conditions for investigational use of new animal drugs are codified under part 511 (21 CFR part 511). If a new animal drug is only for tests in vitro, or testing in laboratory research animals, the person distributing the new animal drug must maintain records showing: (1) The name and post office address of the expert or expert organization to whom the drug is shipped; and (2) the date, quantity, batch or code mark for each shipment for a period of 2 years after such shipment or delivery. Prior to shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) The identity of the new animal drug; (2) labeling; (3) a statement of compliance