

comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: November 6, 2001.

Bob Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Information collection from applicants who will respond to Request for Applications for funding of seven OCS competitive grants.

OMB No.: 0970-0062.

Description: The Office of Community Services (OCS) is requesting approval to continue the use of its program announcements to collect information which will enable the agency to determine which projects to fund and the amount of the grant awards. The programs covered include: Community Food and Nutrition; Community Economic Development Discretionary Grants Program; Low Income Home Energy Assistance Program Residential Energy Assistance Challenge Option Program (REACH); LIHEAP Clearinghouse T&TA; Job Opportunities for Low-Income Individuals; CSBG Training and Technical Assistance and Capacity Building; and Family Violence Prevention and Services Program.

Information collected from the requirements contained in these program announcements will be the sole source of information available to OCS in reviewing applications leading to awards of discretionary grants to eligible applicants.

The application forms that will be used contain information for competitive review in accordance with the program announcements' guidelines. The data provided is necessary to compute the amount of the grant in relation to proposed project activities by the ACF Grant Officers.

OMB recommended that ACF submit one information collection package covering all OCS discretionary program announcements, since the same application form is used in each announcement. This information collection was last approved in 1998; it is due to expire October 31, 2001. Since the last approval, we have added the Residential Energy Assistance Challenge Option Program (REACH) as an additional Low Income Home Energy Assistance Program.

Respondents: State and local governments, Indian tribes, not-for-profit organizations.

Annual Burden Estimates:

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|-----------------------|------------------------------------|-----------------------------------|--------------------|
| Community Economic Development Announcement | 250 | 1 | 28 | 7,000 |
| Community Food and Nutrition Announcement | 250 | 1 | 10 | 2,500 |
| LIHEAP Clearinghouse (RFP) T&TA | 5 | 1 | 10 | 50 |
| LIHEAP Reach Announcement | 45 | 1 | 10 | 450 |
| JOLI Announcement | 170 | 1 | 30 | 5,100 |
| T&TA (CSBG) Announcement | 70 | 1 | 10 | 700 |
| Family Violence Announcement | 150 | 1 | 30 | 4,500 |
| Estimated Total Annual Burden Hours: | | | | 20,300 |

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.

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, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: November 1, 2001.

Bob Sargis,

Reports Clearance Officer.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N-2079]

Draft Guidance for Reviewers on the Integration of Study Results To Assess Concerns About Human Reproductive and Developmental Toxicities; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for reviewers entitled "Integration of Study

Results to Assess Concerns About Human Reproductive and Developmental Toxicities." This draft guidance describes a process for estimating human developmental and reproductive risks as a result of drug exposure when definitive human data are unavailable. The integration process is intended to estimate the likelihood a drug will increase the risk of adverse human developmental or reproductive effects.

DATES: Submit written or electronic comments on the draft guidance by March 13, 2002. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD-240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. See