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.

[FR Doc. 01–28384 Filed 11–9–01; 8:45 am]

BILLING CODE 4184–01–M

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.

[FR Doc. 01–28385 Filed 11–9–01; 8:45 am]

BILLING CODE 4184–01–M

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

the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*.

FOR FURTHER INFORMATION CONTACT: Joseph J. DeGeorge, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration,1451 Rockville Pike, Rockville, MD 20852, 301–594–5476.

SUPPLEMENTARY INFORMATION:

I. Background

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 reproductive and development risks as a result of drug exposure. The integration process is intended to estimate the likelihood a drug will increase the risk of adverse human reproductive or developmental effects. The process is based on the evaluation of a complete set of reproductive and general toxicology studies conducted in animals, pharmacokinetics, and the absorption and distribution of metabolic elimination (ADME) studies conducted in animals and humans. The evaluation also compares animal and human drug-induced pharmacodynamic responses, drug metabolism and disposition, drug-induced pharmacologic and toxic effects, and drug exposures in animal studies versus those at the highest recommended dose in humans.

An earlier version of this integration tool was presented in a public meeting announced on May 4, 1999 (64 FR 23844), and held on June 24, 1999. The draft integration tool, slides from the presentations at the meeting, and comments received subsequent to the meeting were placed on the FDA Web site and in docket number 99N–2079. This draft guidance incorporates modifications as a result of the public meeting and comments submitted to the public docket.

The type and extent of the available toxicology data may vary depending on the biologic actions of the product, test systems available for studying the compound, and other factors. In some instances, the data may not include all desirable reproductive toxicology, general toxicology, pharmacokinetics, and ADME studies. Such limitations of the available data may preclude use of the integration process (e.g., often the case for biologic products). However, even if the integration process cannot be used, the product should be evaluated to the greatest extent possible in accordance with sound scientific principles and the considerations described in this document.

For purposes of this draft guidance, all reproductive risks are divided into one of two broad categories of toxicity—reproductive and developmental toxicity, which are further subdivided into seven classes of toxicity. The three classes of reproductive toxicity include: Effects on fertility, parturition, and lactation. The four classes of developmental toxicity include: Mortality, dysmorphogenesis (structural alterations), alterations to growth, and functional toxicities. For a given drug, each class of toxicity should ordinarily be assessed individually.

The criteria presented in the draft guidance are derived from a limited sample of pharmaceuticals where the clinical outcomes are reasonably well defined. The Center for Drug Evaluation and Research (CDER) believes that using specific criteria and benchmark values to assess the potential to increase risk to humans for adverse reproductive and developmental outcomes will result in a more unbiased and uniform evaluation. CDER also believes this approach will help identify specific areas of additional information about a pharmaceutical that would be useful in more fully defining risk and allow specific analysis of areas of disagreement that influence the risk evaluation. CDER is particularly interested in comment on the appropriateness of the values used to define levels of increased risk for products with positive signals for reproductive or developmental toxicity and on experience in applying the outlined evaluation approach using information that may exist in public and commercial domains.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on ''Integration of Study Results to Assess Concerns About Human Reproductive and Developmental Toxicities.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments on the draft guidance. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: November 1, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–28258 Filed 11–9–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0195]

Draft ''Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations;'' Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Guidance for FDA Staff: The Leveraging Handbook, An Agency Resource for Effective Collaborations'' dated November 2001. The draft guidance document, when finalized, is intended to provide information to assist FDA staff in creating and implementing effective collaborations consistent with relevant legal, ethical, and policy considerations. FDA and its stakeholders use collaborations to take advantage of and amplify the unique resources possessed by each to address a variety of public health issues. The draft guidance document enumerates factors that FDA employees should consider, and the procedures they should follow, when planning a leveraged collaboration.

DATES: Submit written or electronic comments on the draft guidance to