epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production use. HHS has delegated program responsibility to CDC.

In addition, an MOU was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or ''Superfund''). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

*Purpose:* The SRS Dose Reconstruction Project supports research that evaluates past releases of radioactive materials and chemicals from the SRS to the surrounding environment. The CDC and RAC are conducting a study of the SRS to determine whether past nuclear materials production caused offsite health effects. Phase I of that study involved the most comprehensive review of records ever undertaken at any of the U.S. Weapons facilities. Phase II of the study, to be completed in August of 1999, uses that information to estimate past releases of radionuclides and chemicals from the SRS. The research team has also analyzed the offsite environmental measurements of these materials performed since the early 1950's. Phase II of the project is nearing completion, with the release of a draft, 1400-page report for technical peer review in February of 1999.

This series of public meetings will present the study's draft results, and will provide an opportunity for individuals to comment on the research and to provide additional information concerning past SRS operations.

Public input and the promise to provide clear and easily obtained sources of public information are important parts of this study, from start to finish. Newsletters have been published regularly to provide updates on the progress of the research. Fact sheets highlighting specific research topics have been released throughout the work as well.

*Contact Person for More Information:* Paul G. Renard, Project Officer, Radiation Studies Branch, Division of Environmental Hazards and Health Effects, NCEH, CDC, 4770 Buford Highway, NE, M/S F–35, Atlanta, Georgia 30341–3724. Telephone 770/488–7040, fax 770/488–7044.

The Director, Management Analysis and Services Office has been delegated the authority to sign Federal Register notices pertaining to announcements of meetings and other committee management activities, for both CDC and ATSDR.

Dated: January 20, 1999.

**Carolyn J. Russell,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 99–1837 Filed 1–26–99; 8:45 am]

**BILLING CODE 4163–18–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

### Proposed Information Collection Activity; Comment Request

*Proposed Project:*

*Title:* Family Preservation and Family Support (FP/FS) Services Implementation Study—State Level Data Collection

*OMB No.:* 0970–0137

*Description:* The Omnibus Budget Reconciliation Act of 1993 (OBRA 93) established title IV–B, subpart 2 of the Social Security Act (42 U.S.C. 62–628) to provide funds to states for the development of family preservation and family support programs and services. Subpart 2, Section 435 of OBRA 93 requires the Secretary of HHS to evaluate the effectiveness of programs carried out under the legislation. The Adoption and Safe Families Act of 1997, P.L. 105–89, reauthorizes the family preservation and family support programs and services and amended Section 431 [42 U.S.C. 639a] to add two new services: Time-Limited Family Reunification Services and Adoption Promotion and Support Services.

In this second phase of data collection, the five data collection instruments, which were used during the previous phase (1996–1999) will be used with minor changes to reflect the language and amendments of the 1997 reauthorization of the program. Each instrument is geared toward obtaining information from individuals/agencies who will have a slightly different perspective on the context, planning, and implementation of the FP/FS legislation. The data collection instruments will seek information on the programs and services funded, the goals of the planning process, populations targeted, reform efforts initiated, the relationship between family preservation, family support and child welfare, staffing and training, and information systems. Data collection on states planning and implementation experiences will be accomplished through semi-structured interviews with state officials and other key stakeholders who are knowledgeable about child welfare.

Both qualitative and quantitative analyses will be completed to highlight the process states employ to implement the legislation coordinate with other funding sources, develop new systems, and improve service delivery systems. Data analyses also will focus on the impact of legislative changes on the state implementation of the program and comparisons of state implementation before and after the legislative reauthorization. Information obtained from data analyses will provide feedback to ACF in the determination of future policy guidance and the scope and nature of technical assistance to be provided to states. The information will also provide direct feedback to states concerning successful implementation strategies.

*Respondents:* State, Local or Tribal government and Not-for-Profit Institutions.

ANNUAL BURDEN ESTIMATES

| Instrument | Number of respondents | Number of responses per respondent | Average burden hours per response | Total burden hours |
|---|---|---|---|---|
| Traditional Child Welfare Staff | 40 | 1 | .54 | 21.60 |
| Program Coordinator | 10 | 1 | 1.00 | 10.00 |
| Stakeholders | 80 | 1 | 1.00 | 80.00 |
| Family Preservation Staff | 10 | 1 | .75 | 7.50 |
| Family Support Staff | 10 | 1 | 1.00 | 10.00 |

*Estimated Total Annual Burden Hours:* 129.10.

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 Information Services, 370 L'Enfant Promenade, S.W., Washington, D.C. 20447, Attn: ACF Reports Clearance Officer. 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: January 21, 1999.

**Bob Sargis,**

*Acting Reports Clearance Officer.*

[FR Doc. 99–1860 Filed 1–26–99; 8:45 am]

**BILLING CODE 4184–01–M**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. 98N–0811]**

### Agency Information Collection Activities: Proposed Collection; Comment Request; Guidance for Industry: Designation, Development, and Application Review for Products in Fast-track Drug Development Programs

**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 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 proposed collection of information concerning submissions by sponsors of investigational new drugs and applicants for new drug approvals or biological licenses that request fast-track designation and the guidance for industry on fast-track drug development programs.

**DATES:** Submit written comments on the collection of information by March 29, 1999.

**ADDRESSES:** Submit written comments on the collection of information to the Dockets Management Branch (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:** JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

**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 of the 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 listed as follows.

With respect to the following collection of information, FDA invites comment on: (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.

**Guidance for Industry: Designation, Development, and Application Review for Products in Fast-track Drug Development Programs (OMB Control Number 0910–0389)—Extension**

Section 112(a) of the Food and Drug Administration Modernization Act of 1997 (FDAMA) (Pub. L. 105–115) amends the Federal Food, Drug, and Cosmetic Act (the act) by adding section 506 (21 U.S.C. 356) and authorizes FDA to take appropriate action to facilitate the development and expedite the review of new drugs, including biological products, intended to treat a serious or life-threatening condition and that demonstrate a potential to meet an unmet medical need. The issuance of the guidance will be under section 112(b) of FDAMA, which requires the agency to issue guidance regarding fast-track policies and procedures within 1 year of the date of enactment of FDAMA, November 21, 1997. The guidance will discuss collections of information that are expressly specified under section 506 of the act, other sections of the Public Health Service Act (the PHS Act), or implementing regulations. For example, under section 506 of the act, an applicant who seeks fast-track designation must submit a request to FDA. Some of the support for such a request may be required under regulations, such as parts 312, 314, and 601 (21 CFR parts 312, 314, and 601), which specify the types and format of information and data that should be submitted to FDA for evaluation of the safety and effectiveness of investigational new drug applications (IND's) (part 312), new drug applications (part 314), or biological license applications (part 601). The guidance will describe three general areas involving collection of information: Designation requests, premeeting packages, and requests to submit portions of an application. Of these, designation requests, and premeeting packages in support of obtaining a fast-track program benefit will provide for additional collections of information not provided elsewhere in statute or regulation. Information in support of fast-track designation or fast-track program benefits that has previously been submitted to the agency, may, in some cases, be incorporated by referring to them rather than by resubmission. In some instances, a summary of data and information may be submitted in support of fast-track designation or fast-