

ADDRESSES: Submit written requests for single copies of the document to First Cycle Review, Office of Planning (HFP-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/pdufa/default.htm>. Submit written comments on the document to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carolyn L. Staples, Office of Planning (HFP-10), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-5274.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Statement of Work for the Evaluation of First Cycle Review Performance." FDA requests comment on the document, which describes a study to evaluate issues associated with FDA's performance of first cycle reviews of NDAs, BLAs, and efficacy supplements.

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (PDUFA III). In conjunction with the passage of PDUFA III, FDA agreed to certain performance goals and procedures that were described in an enclosure to a June 4, 2002, letter from the Secretary of Health and Human Services, Tommy Thompson, to Congress entitled "PDUFA Reauthorization Performance Goals and Procedures" (PDUFA Goals and Procedures). One of the goals relates to FDA's performance of first cycle reviews of original NDAs, BLAs, and efficacy supplements (PDUFA Goals and Procedures, section 10). Specifically, FDA agreed to retain an independent expert consultant to undertake a study to evaluate issues associated with the agency's conduct of first cycle reviews. The study is intended to assess the following: (1) Current first cycle review performance and any changes that occur after FDA publishes guidance on Good Review Management Principles (GRMPs), (2) the first cycle review history of all NDAs for new molecular entities and all BLAs during PDUFA III, and (3) the effectiveness of FDA's staff training regarding GRMPs. FDA agreed to develop a statement of work for the

study and to provide the public with an opportunity to review and comment on the statement of work before the study is implemented.

In accordance with one of the PDUFA goals, the document being made available for public comment today is the statement of work developed by FDA. FDA intends to award a contract that would include, among other tasks, the performance of the study. The document, as currently written, will be included in the RFP as a sample statement of work. However, the statement of work is not yet final. FDA will consider all comments received in finalizing the statement of work prior to assigning the task under the contract.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written comments on the document. 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 document made available today and the received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: October 8, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA Reports Clearance Officer on (301) 443-7978.

Comments are invited on: (a) Whether the proposed collections of information are 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) ways to enhance 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.

Proposed Project: National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program, Phase Four—New—SAMHSA's Center for Mental Health Services (CMHS) is conducting Phase IV of this national evaluation project among grantees newly funded in FY 2002 and 2003. The national evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program will collect data on child mental health outcomes, family life, and service system development and performance.

Data will be collected on 23 service systems, and approximately 5,281 children and families. Data collection for this evaluation will be conducted over a five-year period. The core of service system data will be collected every 18 months throughout the 5-year evaluation period, with a sustainability survey conducted in selected years. Service delivery and system variables of interest include the following: Maturity of system of care development, adherence to the system of care program model, and client service experience. The length of time that individual families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation.

Child and family outcomes of interest will be collected at intake and during subsequent follow-up sessions at six-month intervals. The outcome measures include the following: Child symptomatology and functioning, family functioning, material resources, and caregiver strain. In addition, an evidence-based treatment study will examine the relative impact of evidence-based treatments focused on substance use prevention within 2 systems of care. Time-limited studies addressing the cultural competence of services and the role of primary care providers in systems of care will be conducted at selected points during the evaluation period. Internet-based technology will be used for collecting data via Web-based surveys and for data entry and management. The average annual respondent burden is estimated below. The estimate reflects the average number of respondents in each respondent category, the average