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 9, 1999.

Bob Sargis,

Acting Reports Clearance Officer.

[FR Doc. 99–6291 Filed 3–15–99; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 93N–0445]

Agency Information Collection Activities; Announcement of OMB Approval; Financial Disclosure by Clinical Investigators

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Financial Disclosure by Clinical Investigators'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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: In the **Federal Register** of December 31, 1998 (63 FR 72171), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0396. The approval expires on March 31, 2002. A copy of the supporting statement for this information collection is available on the Internet at ''http://www.fda.gov/ohrms/dockets''.

Dated: March 9, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6339 Filed 3–15–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–0362]

Site Specific Stability Data for Drug and Biologic Applications; Public Meeting; Request for Comment

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comment.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting on site specific stability data for drug and biologic applications. The agency has scheduled the public meeting to discuss scientific issues related to a section of the draft guidance entitled ''Draft Guidance for Industry—Stability Testing of Drug Substances and Drug Products.'' Specifically, the agency will discuss the section of the draft guidance entitled ''Site-Specific Stability Data for Drug and Biologic Applications.'' The agency invites comments on issues related to the meeting.

DATES: The public meeting will be held on March 31, 1999, from 9 a.m. to 2 p.m. Submit written notices of participation by March 24, 1999. Submit written comments on the specific issues of the meeting by June 14, 1999.

ADDRESSES: The public meeting will be held at the Holiday Inn Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814. Submit written notices of participation to Kimberly L. Topper or Angie Whitacre (addresses below). Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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.

FOR FURTHER INFORMATION CONTACT: Kimberly L. Topper or Angie Whitacre, Center for Drug Evaluation and Research (HFD–21), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–7001, or e-mail topperk@cder.fda.gov.

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by March 24, 1999. Oral presentations from the public will be scheduled. Time allotted for each presentation may be limited. Those persons desiring to make formal oral presentations should notify the contact person before March 24, 1999 (providing name, firm name, address, and telephone number), and submit a brief statement of the general nature of the evidence or arguments they wish to present, and an indication of the approximate time requested to make their presentation.

Dated: March 9, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–6301 Filed 3–15–99; 8:45 am]

BILLING CODE 4160–01–F

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: Phase II of the National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program

(OMB No. 0930–0192, Revision)—SAMHSA's Center for Mental Health Services (CMHS) is conducting Phase II of this national evaluation project. To address the research questions in the national evaluation, a longitudinal quasi-experimental design is being used that includes data collection in all grantee sites and comparison sites over a five year period. Data collection methods include interviews with caregivers and youth, site visits, case record reviews, service diaries, and provider surveys. Phase II collects data on child mental health outcomes, family life, and service system development and performance. Child and family outcomes of interest include the following: child symptomatology and functioning, family functioning and material resources, and caregiver strain. The length of time that families will participate in the study ranges from 18 to 36 months depending on when they enter the evaluation. Service system variables of interest include the following: maturity of system of care development, adherence to system of care principles, coordination and linkages among agencies, and congruence between family services planned versus those received.

This revision to the currently approved information collection activities involves: (1) two additional grantee sites added to Phase II after the original OMB package was approved, and (2) the addition of a strengths-based measure of child behaviors. This measure is closely aligned with the strengths-based focus of the grant program and will assess the effects of the initiative on child strengths and resiliency; no additional burden is imposed by addition of the strengths-based measurement in the previously approved sites because it has been determined that the burden associated with the new instrument is offset for shorted times of administration by two of the currently approved instruments. Automated collection techniques are not cost-effective for this study. The average annual respondent burden is estimated below.

Respondents	Number of respondents	Responses/ respondent	Burden/ response (Hours)	Total burden hours (Annualized)
Currently approved	.....	.....	.....	18, 458
New Sites: Caregivers	506	1.16	1.96	1,150
Youth	304	1.10	.88	294
Providers	56	.80	.75	34
Sub-Total	.....	.....	.....	1,478
New Total	.....	.....	.....	19,936

Send comments to Nancy Pearce, SAMHSA Reports Clearance Officer, Room 16–105, Parklawn Building, 5600 Fishers Lane, Rockville, MD 20857. Written comments should be received within 60 days of this notice.

Dated: March 9, 1999.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 99–6312 Filed 3–15–99; 8:45 am]

BILLING CODE 4162–20–P

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: Phase I of the National Evaluation of the Comprehensive Community Mental Health Services for Children and Their Families Program

(OMB No. 0930–0171, Extension, no change)—The Center for Mental Health Services (CMHS) is seeking OMB approval for a 1-year extension of this evaluation of integrated child mental health service systems. The core and comparison studies of the evaluation collect information on child and family demographics, child mental health status, and service system development. In the core study, data are collected from children and families at intake into services, six months later, and every 12 months thereafter while the children remain in services. In the comparison study component, information is collected at intake, 6 months, 12 months, 24 months, and annually thereafter. In both studies, data were collected annually from grantees' administrators and providers. This request is to extend OMB clearance to allow: (1) continued data collection in two core study sites for two months, and (2) completion, by the end of the approval period, of data collection in the comparison study component sites. The response burden for this extension is as follows: