have been submitted under § 60.24. Three regulatory review periods have been altered. Two due diligence petitions have been submitted to FDA under § 60.30. There have been no requests for hearings under § 60.40 regarding the decisions on such petitions.

In the **Federal Register** of May 19, 2004 (69 FR 28929), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
60.24(a)	7	1	7	100	700
60.30	2	0	2	50	100
60.40	0	0	0	0	0
Total					800

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: August 12, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18976 Filed 8–18–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D–0112]

Guidance for Industry on Independent Consultants for Biotechnology Clinical Trial Protocols; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a document entitled ''Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols,'' dated August 2004. The guidance document provides guidance to sponsors of clinical trials for certain products on when and how to request from FDA the engagement of an independent consultant to participate in the review of protocols for clinical studies intended to serve as the primary basis of claims of efficacy. This guidance document finalizes the draft guidance of the same title dated May 2003.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448; or the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the CBER voice information system at 1–800–835–4709 or 301–827–1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written comments on the guidance to the Division of Dockets Management (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: Nathaniel L. Geary, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–6210; or Susan S. Johnson, Center for Drug Evaluation and Research, Office of New Drugs (HFD–20), 5515 Security Lane, suite 7215, Rockville, MD 20852, 301–594–3937.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled ''Guidance for Industry: Independent Consultants for Biotechnology Clinical Trial Protocols'' dated August 2004. 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). A letter from the Secretary of Health and Human Services (June 4, 2002), to Congress concerning PDUFA III included an addendum containing the performance goals and programs to which FDA committed as a means of facilitating the development and review of products subject to PDUFA III. One commitment was for FDA to establish a program to allow sponsors of clinical trials for certain products to request that FDA engage an independent consultant to participate in the review of protocols for clinical studies that are intended to serve as the primary basis of claims of efficacy. This guidance document is intended to explain when and how a sponsor may take advantage of this program.

This guidance document finalizes the draft guidance document of the same title dated May 2003 (68 FR 24486, May 7, 2003). The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on this topic. 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, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

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

Dated: August 11, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–18974 Filed 8–18–04; 8:45 am]

BILLING CODE 4160–01–S

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: Evaluation for Ecstasy, Other Club Drugs, Methamphetamine, and Inhalants Prevention Initiative—NEW

SAMHSA's Center for Substance Abuse Prevention (CSAP) under the Substance Abuse and Mental Health Services Administration (SAMHSA) will request OMB approval for two new instruments: the Targeted Capacity Expansion and Process Measure Questionnaire (TCEPMQ), and the Direct Service Intervention Dosage Data Form (DSIDDF). These instruments will be used to conduct an evaluation of capacity building, process, and project level dosage for the Ecstasy, Other Club Drugs, Methamphetamine, and Inhalant Prevention Initiative (the Initiative). These instruments will permit the grantee sites to report data about their progress in conducting targeted capacity expansion and in delivering direct service interventions.

The TCEPMQ and the DSIDDF are instruments designed to capture project level information. The TCEPMQ captures information from the projects about their project implementation and whether the project is being implemented as planned; the types of needs assessments conducted and the findings of the needs assessments; measures of awareness of Ecstasy, other club drug, methamphetamine and inhalant problems and openness to prevention efforts; measures of the projects' relationship-building activities, such as who they collaborate with, how often, and the effectiveness of these relationships; measures of their work to improve organizational and community resources; measures of contextual factors that may affect their planned activities; and a description of the effect of their capacity building activities on the community. The TECPMQ contains a total of 41 questions, 20 of which have closed-ended responses, and 21 of which require open-ended narrative responses.

The DSIDDF is designed to collect information about the projects' implementation of evidence-based prevention programs and any changes they made to the programs. The instrument also captures information about program dosage and fidelity to the model. The DSIDDF contains a total of 10 questions, 7 of which have closed-ended responses and 3 of which have open-ended, narrative responses. By collecting this information, CSAP will be able to assess the projects' progress in implementing targeted capacity expansion within the funded communities.

These electronic, standard instruments will facilitate accurate and appropriate data collection and will ensure that consistent data are collected from all projects. The practical utility of using such standard instruments is much higher than relying on narrative reports, allowing for immediate analysis and prompt technical assistance to sites experiencing program difficulties.

The estimated time needed to complete the TCEPMEQ is 3.75 hours and 2 hours for the DSIDDF. After the projects have completed their first submission of these instruments, there data will be pre-filled, which will further reduce the time burden on the respondents for the next three quarterly submission. By providing pre-filled responses, respondents will only need to provide information for those questions in which their responses have changed. The annual burden estimates for this activity are shown below:

Instrument	Number of respondents		Estimated quarterly respondent burden (by hour)				Total annual hourly respondent burden (total number of burden hours for all respondents)
	Ecstasy and other club drugs	Methamphetamine and inhalants	Quarter 1	Quarter 2	Quarter 3	Quarter 4	
TCEPMQ	12	20	*3.75	2	2	2	9.75 (312)
DSIDDF	11	19	2	.5	.5	.5	3.5 (105)
Totals	12	20	5.75	2.4	2.5	2.5	13.25 (417)

*This includes one hour extra for projects to read the related Administration Guide the first time only.

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 by October 18, 2004.

Dated: August 6, 2004.

Anna Marsh,

Executive Officer, SAMHSA.

[FR Doc. 04–18648 Filed 8–18–04; 8:45 am]

BILLING CODE 4162–20–M

DEPARTMENT OF THE INTERIOR

Geological Survey

Scientific Earthquake Studies Advisory Committee

AGENCY: U.S. Geological Survey.