ADDRESSES: Submit written requests for single copies of the draft guidance to the Drug Information Branch (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Karl K. Lin, Center for Drug Evaluation and Research (HFD–715), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3093.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Statistical Aspects of the Design, Analysis, and Interpretation of Chronic Rodent Carcinogenicity Studies of Pharmaceuticals.'' Assessment of the risk of drug exposure in humans includes an assessment of carcinogenicity in tests in rodents. In a carcinogenicity study of a new drug using a series of increasing dose levels, statistical tests are an important component of the analysis. The Division of Biometrics in the Office of Biostatistics, CDER is responsible for conducting statistical reviews of long-term animal (rodent) carcinogenicity studies of pharmaceuticals submitted by drug sponsors to FDA.

In statistical reviews of carcinogenicity studies, statisticians evaluate the validity of the designs and the appropriateness of methods of data analysis used by the sponsor. They also use raw study data in electronic form to perform additional statistical analyses.

The purpose of this document is to provide guidance to sponsors on statistical issues related to the design of animal carcinogenicity experiments, methods of analysis of tumor data, interpretation of study results, presentation of data and results in reports, and the submission of tumor data to FDA statistical reviewers.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115; 65 FR 56468, September 19, 2000). The draft guidance represents the agency's current thinking on the statistical aspects of the design, analysis, and interpretation of chronic rodent carcinogenicity studies of pharmaceuticals. 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: April 30, 2001.

Ann M. Witt,

Acting Associate Commissioner for Policy.

[FR Doc. 01–11450 Filed 5–7–01; 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: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a list of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

Substance Abuse Prevention and Treatment (SAPT) Block Grant Application Guidance and Instructions, FY 2002–2004 (OMB No. 0930–0080, Revision)

Sections 1921 through 1935 of the Public Health Service Act (U.S.C. 300x–21 to 300x–35) provide for annual allotments to assist States to plan, carry out, and evaluate activities to prevent and treat substance abuse and for related activities. Under the provisions of the law, States may receive allotments only after an application is submitted and approved by the Secretary, DHHS. For the federal fiscal year 2002–2004 SAPT block grant application cycles, the Substance Abuse and Mental Health Services Administration (SAMHSA) will provide States with revised application guidance and instructions to implement changes made by Public Law 106–310, signed by the President on October 17. Revisions to the previously-approved application resulting from the new SAMHSA authorizing legislation reflect the following changes: (1) Section 1922(a) under which States were required to use 35% of the funds on drug related activities and 35% on alcohol related activities (42 U.S.C. 300x–22) is repealed. (2) The Section 1925 requirement for the States to maintain a revolving fund of $100,000 to assist with half way houses for persons recovering from drug or alcohol abuse is now made optional (42 U.S.C. 300x–25). (3) Section 1930, which requires the States to maintain their financial support for substance abuse services at a level equal to the average of what they had spent the previous two years, is amended to permit non-recurring expenditures for a singular purpose to be excluded from the calculation of the Maintenance of Effort (MOE) requirement (42 U.S.C. 300x–30). (4) Section 1952 is amended to allow any amount paid to a State for a fiscal year to be available for obligation and expenditure until the end of the fiscal year following the fiscal year for which the amounts were paid, in effect giving a State two years to obligate and spend (42 U.S.C. 300x–62).

In addition, changes are being made to the annual reporting requirements associated with Section 1926 (42 U.S.C. 300x–26), which requires States to have in effect a law prohibiting access and distribution of tobacco products to minors under age 18. In Section II, the following changes are being made with respect to Goal #8 and Attachment G: (1) In Goal #8, States will not be required to report on activities that were reported in previous applications (i.e., the requirement to report on prior year compliance information is eliminated). (2) In Attachment G: (a) questions are re-ordered so they are in chronological order to facilitate reporting on compliance activities; (b) seven of the nine questions are revised to define more precisely the information that SAMHSA needs in order to review and approve applications and eliminate duplication in State reporting; (c) Matrix

7a has been renamed Form G3, and Form G3 now requires States to report specific ages of the youth inspectors rather than age ranges.

ANNUAL REPORTING BURDEN

	Number of respondents	Responses per respondent	Hours per response	Total burden
Sections I–III—Red Lake Indians	[1] 1	1	530	530
Sections I–III—States and Territories	59	1	563	33,217
Section IV–A	40	1	50	2,000
Section IV–B	20	1	42	840
Total				36,587

[1] Red Lake Indian Tribe is not subject to tobacco requirements.

Written comments and recommendations concerning the proposed information collection should be sent within 30 days of this notice to: Stuart Shapiro, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: May 1, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–11512 Filed 5–7–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Cooperative Agreements with Single State Agencies for Alcohol and Other Drug Abuse for Conducting Evaluations

AGENCY: Center for Substance Abuse Treatment, Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Cooperative Agreements with Single State Agencies for Alcohol and Other Drug Abuse for Assistance to States for Conducting Evaluations of their Substance Abuse Treatment Services.

SUMMARY: This notice is to inform the public of planned cooperative agreements that the Substance Abuse and Mental Health Services Administration (SAMHSA) Center for Substance Abuse Treatment (CSAT), under its State Treatment Needs Assessment Program (STNAP), intends to award to Single State Agencies (SSAs) for Alcohol and Other Drug Abuse. In fiscal year 2001, CSAT has approximately $2.1 million available for 7 to 9 awards. Awards will be made if the applications are scored by the initial review group and concurred with by the CSAT National Advisory Council.

Eligibility for cooperative agreements is limited to SSAs for Alcohol and Other Drug Abuse because the States have statutory responsibility for developing and submitting services needs assessment estimates in order to receive a Substance Abuse Prevention and Treatment (SAPT) Block Grant. By providing assistance to the States for conducting evaluations of their substance abuse treatment services, CSAT, under its STNAP, seeks to help States to determine methods for improving the availability and quality of treatment. The STNAP objectives are to: assist States to take advantage of existing data to develop estimates of need for services and report these data on the annual SAPT Block Grant application; assist States to develop and institutionalize their capability to use data that already exist and to manage data collection and analyses, as needed, to supplement existing data sources; assist States to conduct common assessment studies needed to augment their existing data and to improve the opportunities for aggregation of data across States; and allow for aggregation of data across States for SAMHSA/CSAT to use in secondary analyses, multi-State comparisons, and for augmenting other information collected within SAMHSA.

Authority: Cooperative agreements with SSAs for Alcohol and Other Drug Abuse will be made under the authority of section 1935 (b)(1)(C) and (b)(3) of the Public Health Service Act, as amended (42 USC 300x-35), and section 1929. The Catalog of Federal Domestic Assistance number is 93.238.

FOR FURTHER INFORMATION CONTACT: Nita Fleagle, CSAT, SAMHSA, Rockwall II, Suite 840, 5600 Fishers Lane, Rockville, MD 20857; telephone (301) 443–8572; e-mail: nfleagle@samhsa.gov

Dated: May 1, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–11448 Filed 5–7–01; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4650–N–32]

Notice of Submission of Proposed Information Collection to OMB; Emergency Comment Request for HUD Alternative for SF 424 Forms, Application for Federal Assistance and Attendent Forms

AGENCY: Office of The Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: The proposed information collection requirement described below has been submitted to the Office of Management and Budget (OMB) for emergency review and approval, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* May 15, 2001.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments must be received within seven (7) days from the date of this Notice. Comments should refer to the proposal by name/or OMB approval number) and should be sent to: Joseph F. Lackey, Jr., HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, Q, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410; e-mail Wayne_Eddins@HUD.gov; telephone (202) 708–2374. This is not a toll-free number. Copies of available documents