Dated: June 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–15780 Filed 6–22–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0132]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Institutional Review Boards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments on the collection of information by July 25, 2001.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Karen L. Nelson, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Institutional Review Boards (OMB Control Number 0910–0130)—Extension

When reviewing clinical research studies regulated by FDA, IRBs are required to create and maintain records describing their operations, and make the records available for FDA inspection when requested. These records include: Written procedures describing the structure and membership of the IRB and the methods which the IRB will use in performing its functions; the research protocols, informed consent documents, progress reports, and reports of injuries to subjects submitted by investigators to the IRB; minutes of meetings showing attendance, votes and decisions made by the IRB, the number of votes on each decision for, against, and abstaining, the basis for requiring changes in or disapproving research; records of continuing review activities; copies of all correspondence between investigators and the IRB; statement of significant new findings provided to subjects of the research; and a list of IRB members by name, showing each member's earned degrees, representative capacity, and experience in sufficient detail to describe each member's contributions to the IRBs deliberations, and any employment relationship between each member and the IRBs institution. This information is used by FDA in conducting audit inspections of IRBs to determine whether IRBs and clinical investigators are providing adequate protections to human subjects participating in clinical research.

In the **Federal Register** of March 30, 2001 (66 FR 17427), the agency requested comments on the proposed collection of information. There were no comments received.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
56.115	2,000	14.6	29,200	4.5	131,400
Total					131,400

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

The recordkeeping requirement burden is based on the following formula: Approximately 2,000 IRBs review FDA-regulated research involving human subjects annually. The burden for each of the paragraphs under § 56.115 has been considered as one for the purpose of estimating the burden. Each paragraph cannot reasonably be segregated from one another because all are interrelated. FDA has about 2,000 IRBs in its inventory. The 2,000 IRBs meet on an average of 14.6 times annually. The agency estimates that approximately 4.5 hours of person time per meeting are required to transcribe and type the minutes of the meeting; to maintain records of continuing review activities; and to make copies of all correspondence between the IRB and investigator's member records, and written IRB procedures which are approximately five pages per IRB.

In the **Federal Register** of June 9, 1998 (63 FR 31502), the agency requested comments on the proposed collections of information. No significant comments were received.

Dated: June 18, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

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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.

Participant Feedback on Training Under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program II (OMB No. 0930–0195, Extension)—The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) intends to continue to conduct a multi-site assessment of its Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program II until the end of the sites' expenditure of Program II funds (anticipated end date of September 2002). The education programs funded under this cooperative agreement are

designed to disseminate knowledge of the psychological and neuropsychiatric sequelae of HIV/AIDS to both traditional (e.g., psychiatrists, psychologists, nurses, primary care physicians, medical students, and social workers) and non-traditional (e.g., clergy, and alternative health care workers) first-line providers of mental health services.

The multi-site assessment is designed to assess the effectiveness of particular training curricula, document the integrity of training delivery formats, and assess the effectiveness of the various training delivery formats. Analyses will assist CMHS in documenting the numbers and types of traditional and non-traditional mental health providers accessing training; the content, nature and types of training participants receive; and the extent to which trainees experience knowledge, skill and attitude gains/changes as a result of training attendance. The multi-site data collection design uses a two-tiered data collection and analytic strategy to collect information on (1) the organization and delivery of training, and (2) the impact of training on participants' knowledge, skills and abilities.

Information about the organization and delivery of training will be collected from trainers and staff who are funded by these cooperative agreements hence there is no respondent burden. All training participants attending sessions lasting less than 6 hours will be asked to complete a brief feedback form at the end of the training session. Trainees attending sessions lasting 6 hours or longer will be asked to complete brief pre-and post-session feedback questionnaires. A sample of trainees attending sessions lasting 6 hours or longer will also be asked to complete a brief follow-up telephone interview three months after the training session. CMHS has funded seven education sites under the Cooperative Agreement for Mental Health Care Provider Education in HIV/AIDS Program II. The annual burden estimates for this activity are shown below:

Form	Responses per respondent	Estimated number of respondents (× 7 sites)	Hours per response	Total hours
All Sessions				
Session Report Form	1	60 × 7 = 420	0.080	34
Sessions Less than 6 Hours				
Participant Feedback Form	1	600 × 7 = 4200	0.167	701
Neuropsychiatric Participant Feedback Form	1	75 × 7 = 525	0.167	88
Ethics Participant Feedback Form	1	75 × 7 = 525	0.167	88
Sessions 6 hours or Longer				
Pre-Training Participant Inventory	1	200 × 7 = 1400	0.167	234
Post-Training Participant Inventory	1	200 × 7 = 1400	0.250	350
Neuropsychiatric Pre-Training Participant Inventory	1	50 × 7 = 350	0.167	58
Neuropsychiatric Post-Training Participant Inventory	1	50 × 7 = 350	0.250	88
Participant Follow-up Form	1	45 × 7 = 315	0.250	79
Monthly Form Submission				
Monthly Form Mailing	12 per site	84	0.167	14
Total		7,504		1,733

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

Dated: June 18, 2001.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 01–15826 Filed 6–22–01; 8:45 am]

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DEPARTMENT OF THE INTERIOR

National Park Service

Benefits Sharing Environmental Assessment, National Park Service

AGENCY: U.S. Department of the Interior, National Park Service.

ACTION: Notice of intent to prepare an Environmental Assessment for the National Park Service (NPS) concerning the environmental impacts of implementing ''benefits-sharing'' agreements when information derived from research specimens collected from units of the National Park System results in commercial value.

SUMMARY: Pursuant to the provisions of the National Environmental Policy Act of 1969, the National Park Service is preparing an Environmental Assessment of potential environmental impacts of implementing ''benefits-sharing'' agreements for research projects that use research specimens lawfully collected from units of the National Park System. NPS authorizes the collection of research specimens from units of the National Park System for qualified scientific purposes under its regulations (36 CFR 1.6 and 2.5). Occasionally, such research also results in commercial applications. ''Benefits-sharing'' refers to the equitable and efficient exchange of valuable research results, and in some cases, economic resources, between researchers and their institutions or companies and the NPS. Through the Federal Technology Transfer Act of 1986 and other statutes. Congress has attempted to create incentives that optimize the social, environmental and economic benefits that can result from