

this guidance was approved under OMB Control No. 0910-0001 and 0910-0032.

This 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 these topics. 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 to the Division of Dockets Management written or electronic comments on the guidance (see **ADDRESSES**). 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 brackets in the heading of this document. The guidance and received comments may be seen 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 document at either <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: November 13, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04-25748 Filed 11-19-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Health Resources and Services Administration (HRSA) publishes information collection requests under review by the Office of Management and Budget, in compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35). To request a copy of the clearance requests submitted to OMB for review, call the HRSA Reports Clearance Office on (301) 443-1129.

The following request has been submitted to the Office of Management and Budget for review under the Paperwork Reduction Act of 1995:

Proposed Project: The Division of Independent Review Grant Reviewer Recruitment Form—New

HRSA's Division of Independent Review (DIR) is responsible for carrying out the independent review of all eligible applications submitted to HRSA. DIR ensures that the independent review process is efficient, effective, economical and complies with statutes, regulations and policies. The review of applications is performed by people knowledgeable in the field of endeavor for which support is requested and is advisory to individuals in HRSA responsible for making award decisions.

To streamline the collection, selection and assignment of grant reviewers to independent review committees, HRSA will utilize a Web-based data collection form to gather critical reviewer information. The Grant Reviewer Recruitment Form will standardize pertinent categories of reviewer information, such as areas of expertise, occupations, work settings, reviewer experience, and allow maximum use of drop-down menus to simplify for the data collection process. All self-nominated reviewers will be channeled to the Grant Reviewer Recruitment Form. DIR anticipates a monthly volume of approximately 100 self-nominated responses. On a periodic basis, existing HRSA reviewers will be notified and directed to update their profile (via the Grant Reviewer Recruitment Form). HRSA maintains a pool of approximately 5,000 individuals that have previously served on HRSA independent review committees. DIR projects that approximately 3,700 individuals (or 75% of existing reviewers) would comply with instructions to update their profile on the Web-based Recruitment Form.

For existing HRSA reviewers, the amount of time required to complete the Recruitment Form will be abbreviated since HRSA will fill in the Form with previously collected personal information; existing reviewers will focus only on updating changes (e.g., addresses, employer, expertise, occupation) to their profile. The estimate of burden for the HRSA Grant Reviewer Recruitment Form is as follows:

Type of respondent*	Number of respondents	Responses per respondent	Total responses	Minutes per response	Total burden hours
New reviewer	1,200	1	1,200	45	900
Existing reviewer	3,700	1	3,700	30	1850
Total	4,900		4,900		2,750

* Includes two categories of grant reviewers: (1) new or self-nominated reviewers that have never served as a HRSA grant reviewer and (2) existing reviewers that have previously served on a HRSA independent review committee.

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

Dated: November 15, 2004.

Tina M. Cheatham,

Director, Division of Policy Review and Coordination.

[FR Doc. 04-25751 Filed 11-19-04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Cooperative Agreement for the International AIDS Education and Training Center; CFDA 93.145

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice of supplemental award.