TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]—Continued

Type of Survey	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Total					4,000

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

These estimates are based on the expected number of respondents necessary to obtain a statistically significant representation of important consumer segments (e.g., users of relevant regulated products, at-risk population groups), and the number of labeling options that may need to be tested.

Dated: February 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–4210 Filed 2–20–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02D–0028]

Medical Devices; Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA.'' Elsewhere in this issue of the **Federal Register**, FDA is issuing a proposed rule to reclassify cyclosporine and tacrolimus assays from class III to class II when used as an aid in the management of transplant patients. If these devices are reclassified, this draft guidance will serve as the special control for the reclassified devices. This draft guidance is neither final nor in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by April 22, 2002.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance entitled ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance. Submit written comments concerning this draft guidance to the Dockets Management Branch (HFZ–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. Comments are to be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jean M. Cooper, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–1243.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance was developed as a special controls guidance to support the proposed reclassification of cyclosporine and tacrolimus assays from class III to class II. When final, this guidance will replace the document ''Guidance Criteria for Cyclosporine PMAs'' dated January 24, 1992. That document was intended to cover the basic science, clinical experience, and issues identified through the review of premarket approval applications (PMAs) for cyclosporine. The agency has updated that guidance. The revised guidance has been retitled ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA.'' On its own initiative, the agency has included tacrolimus assays in addition to cyclosporine assays in the revised guidance because the tacrolimus assay has the same intended use as an aid in the management of transplant patients. The agency believes it is taking a least burdensome approach by including tacrolimus assays in the revised guidance and will include tacrolimus assays in the proposed reclassification.

II. Significance of the Guidance

The draft guidance, when finalized, will represent the agency's current thinking on cyclosporine and tacrolimus assays. 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 applicable statute and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1380 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. ''Class II Special Controls Guidance Document: Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' will be available at http://www.fda.gov/cdrh/ode/guidance/1380.pdf.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by April 22, 2002. Submit two copies of any comments, 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 may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 11, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–4209 Filed 2–20–02; 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.

Emergency Response Grants Regulations—42 CFR part 51—(OMB No. 0930–0229, Extension)—This rule implements section 501(m) of the Public Health Service Act (42 U.S.C 290aa), which authorizes the Secretary to make noncompetitive grants, contracts or cooperative agreements to public entities to enable such entities to address emergency substance abuse or mental health needs in local communities. The rule establishes criteria for determining that a substance abuse or mental health emergency exists, the minimum content for an application, and reporting requirements for recipients of such funding.

SAMHSA will use the information in the applications to make a determination that the requisite need exists; that the mental health and/or substance abuse needs are a direct result of the precipitating event; that no other local, state, tribal or Federal funding sources available to address the need; that there is an adequate plan of services; that the applicant has appropriate organizational capability; and, that the budget provides sufficient justification and is consistent with the documentation of need and the plan of services.

Eligible applicants may apply to the Secretary for either of two types of substance abuse and mental health emergency response grants: Immediate awards and Intermediate awards. The former are designed to be funded up to $50,000, or such greater amount as determined by the Secretary on a case-by-case basis, and are to be used over the initial 90-day period commencing as soon as possible after the precipitating event; the latter awards require more documentation, including a needs assessment, other data and related budgetary detail. The Intermediate awards have no predefined budget limit. Typically, Intermediate awards would be used to meet systemic mental health and/or substance abuse needs during the recovery period following the Immediate award period. Such awards may be used for up to one year, with a possible second year supplement based on submission of additional required information and data.

This program is an approved user of the PHS–5161 application form, approved by OMB under control number 0920–0428. The quarterly financial status reports in 51d.10(a)(2) and (b)(2) are as permitted by 45 CFR 92.41(b); the final program report, financial status report and final voucher in 51d.10(a)(3) and in 51d.10(b)(3–4) are in accordance with 45 CFR 92.50(b). Information collection requirements of 45 CFR part 92 are approved by OMB under control number 0990–0169. The following table presents annual burden estimates for the information collection requirements of this regulation.

42 CFR citation	No. of respondents	Responses/respondent	Burden/response (hrs.)	Total burden (hrs.)
Immediate award application:				
51d.4(a) and 51d.6(a)(2)	3	1	3	*(9)
51d.4(b) and 51d.6(a)(2)—Intermediate Awards	3	1	10	*(30)
51d.10(a)(1)—Immediate awards—mid-program report if applicable	3	1	2	*(6)
Final report content for both types of award:				
51d.10(c)	6	1	3	18
Total	6	—	—	18

*This burden is carried under OMB control number 0920–0428.

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, DC 20503.

Dated: February 14, 2002.

Richard Kopanda,

Executive Officer, SAMHSA.

[FR Doc. 02–4111 Filed 2–20–02; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4734–N–05]

Notice of Submission of Proposed Information Collection to OMB:

AAF Rent Increase Requirement Pursuant to the Housing Appropriations Act of 1994

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 review, as required by the Paperwork Reduction Act. The Department is soliciting public comments on the subject proposal.

DATES: *Comments Due Date:* March 25, 2002.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB approval number (2502–0507) should be