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

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
99.501(b)(4)	2	1.7	3	2	6
99.501(b)(5)	17	1.8	30	41	1,230
Total Hours					48,644

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Recordkeeping Hours
99.501(a)(1)	172	1.7	297	10	2,970
99.501(a)(2)	172	1.7	297	1	297
99.501(c)	172	1.7	297	1	297
Total Hours					3,564

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

The estimated burden associated with the information collection requirements for this rule is 52,208 hours. In the **Federal Register** of June 9, 1998 (63 FR 31502), the agency requested comments on the proposed collections of information. No comments were received.

Dated: September 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23506 Filed 9–13–02; 8:45 am]

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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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''Class II Special Controls Guidance Document; Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA.'' These assays are used as an aid in the management of transplant patients receiving these drugs. Elsewhere in this issue of the **Federal Register**, FDA is issuing a final rule to reclassify cyclosporine and tacrolimus assays into class II (special controls).

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

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the guidance document entitled ''Class II Special Controls Guidance Document; Cyclosporine and Tacrolimus Assays; Guidance for Industry and FDA'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, 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. Submit written comments concerning this 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*. *See* the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

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

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 21, 2002 (67 FR 7982), FDA published a proposed rule to reclassify cyclosporine and tacrolimus assays from class III (premarket approval) to class II (special controls) after reviewing information contained in reclassification petitions submitted by Dade Behring, Inc., and Microgenics, Inc. FDA also identified the guidance document entitled ''Class II Special Controls Guidance Document; Cyclosporine and Tacrolimus Assays; Draft Guidance for Industry and FDA'' as the special control capable of providing reasonable assurance of safety and effectiveness for these devices. These assays are used as an aid in the management of transplant patients receiving these drugs.

Interested persons were invited to comment on the draft guidance by April 22, 2002. FDA received two comments that were supportive of the proposed reclassification, but these comments suggested specific recommendations for changes to the guidance. The guidance has been revised to reflect consideration of these comments.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance represents the agency's current thinking on special controls for 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. Following the effective date of this final classification rule, any firm submitting a 510(k) premarket notification for a

cyclosporine or tacrolimus test system will need to address the issues covered in the special control guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

III. Electronic Access

In order to receive ''Class II Special Controls Guidance Document; Cyclosporine and Tacrolimus Assays; 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 guidance may also do so using the Internet. The Center for Devices and Radiological Health (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 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 submission, 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; Guidance for Industry and FDA'' will be available at *http://www.fda.gov/cdrh/ode/guidance/1380.pdf*.

IV. Paperwork Reduction Act

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in part three of this guidance has been submitted to OMB for review and was approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the 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 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.

Dated: August 19, 2002.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 02–23507 Filed 9–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4734–N–44]

Notice of Submission of Proposed Information Collection to OMB; Application for Eligibility as a Nonprofit Corporation

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:* October 16, 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 (2502–0057) and should be sent to: Lauren Wittenberg, OMB Desk Officer, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503; Fax number (202) 395–6974; e-mail *Lauren__Wittenberg@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Wayne Eddins, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 Seventh Street, Southwest, Washington, DC 20410; e-mail *Wayne__Eddins@HUD.gov*; telephone (202) 708–2374. This is not a toll-free number. Copies of the proposed forms and other available documents submitted to OMB may be obtained from Mr. Eddins.

SUPPLEMENTARY INFORMATION: The Department has submitted the proposal for the collection of information, as described below, to OMB for review, as required by the Paperwork Reduction Act (44 U.S.C. Chapter 35). The Notice lists the following information: (1) The title of the information collection proposal; (2) the office of the agency to collect the information; (3) the OMB approval number, if applicable; (4) the description of the need for the information and its proposed use; (5) the agency form number, if applicable; (6) what members of the public will be affected by the proposal; (7) how frequently information submissions will be required; (8) an estimate of the total number of hours needed to prepare the information submission including number of respondents, frequency of response, and hours of response; (9) whether the proposal is new, an extension, reinstatement, or revision of an information collection requirement; and (10) the name and telephone number of an agency official familiar with the proposal and of the OMB Desk Officer for the Department.

This Notice also lists the following information:

Title of Proposal: Application for Eligibility as a Nonprofit Corporation.

OMB Approval Number: 2502–0057.

Form Numbers: HUD–3433, HUD–3434, HUD–3435.

Description of the Need for the Information and Its Proposed Use: The application identifies the nonprofits' qualification to successfully sponsor a multifamily housing project. A nonprofit is defined as an entity organized for reasons other than financial gain. The information collected will also be used to identify the nonprofit's motive for sponsoring the project, and identify any contractual relationship that exists between HUD and the nonprofit.

Respondents: Not-for-profit institutions, business or other for-profit.

Frequency of Submission: On occasion.

	Number of respondents	Annual responses	×	Hours per response	=	Burden hours
Reporting Burden:	270	270		3		90