The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 10, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–23457 Filed 9–13–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.–5 p.m., November 7, 2002, 8:30 a.m.–12 p.m., November 8, 2002.

Place: Corporate Square, Building 8, 1st Floor Conference Room, Atlanta, Georgia 30333. Telephone: 404/639–8008.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the Council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters to be Discussed: Agenda items include issues pertaining to improving TB control efforts in the Southeast, community based TB prevention projects, surveillance of TB-related hepatotoxicity and other TB related topics. Agenda items are subject to change as priorities dictate.

For More Information Contact: Paulette Ford-Knights, National Center for HIV, STD, and TB Prevention, 1600 Clifton Road, NE., M/S E–07, Atlanta, Georgia 30333, telephone 404/639–8008.

Agenda items are subject to change as priorities dictate.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** Notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Dated: September 10, 2002.

John Burckhardt,

Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 02–23458 Filed 9–13–02; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0123]

Agency Information Collection Activities; Announcement of OMB Approval; Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Food Canning Establishment Registration, Process Filing and Recordkeeping for Acidified Foods and Thermally Processed Low-Acid Foods in Hermetically Sealed Containers'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 22, 2002 (67 FR 47820), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0037. The approval expires on August 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 10, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–23505 Filed 9–13–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N–0109]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information entitled ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices 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 October 16, 2002.

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: Stuart Shapiro, 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. Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices (OMB Control Number 0910–0390)—Extension.

In the **Federal Register** of November 20, 1998 (63 FR 64555), FDA published a final rule that added a new part 99 (21 CFR part 99) entitled ''Dissemination of Information on Unapproved/New Uses for Marketed Drugs, Biologics, and Devices.''

The final rule implemented section 401 of the Food and Drug

Administration Modernization Act (FDAMA) (Public Law 105–115). In brief, section 401 of FDAMA amended the act to permit drug, biologic, and device manufacturers to disseminate certain written information concerning the safety, effectiveness, or benefits of a use that is not described in the product's approved labeling to health care practitioners, pharmacy benefit managers, health insurance issuers, group health plans, and Federal and State Government agencies, provided that the manufacturer complies with certain statutory requirements. For example, the information that is to be disseminated must be about a drug or device that is being legally marketed; it must be in the form of an unabridged reprint or copy of a peer-reviewed journal article or reference publication; and it must not be derived from another manufacturer's clinical research, unless that other manufacturer has given its permission for the dissemination. The information must be accompanied by certain information, including a prominently displayed statement that the information discusses a use or uses that have not been approved or cleared by FDA. Additionally, 60 days before dissemination, the manufacturer must submit to FDA a copy of the information to be disseminated and any other clinical trial information that the manufacturer has relating to the safety or effectiveness of the new use, any reports of clinical experience that pertain to the safety of the new use, and a summary of such information.

The rule sets forth the criteria and procedures for making such submissions to FDA. Under the rule, a submission would include a certification that the manufacturer has completed clinical studies necessary to submit a supplemental application to FDA for the new use and will submit the supplemental application within 6 months of its initial dissemination of information. If the manufacturer has planned, but not completed, such studies, the submission would include proposed protocols and a schedule for conducting the studies, as well as a certification that the manufacturer will complete the clinical studies and submit a supplemental application no later than 36 months of its initial dissemination of information. The rule also permits manufacturers to request extensions of the time period for completing a study and submitting a supplemental application, and to request an exemption from the requirement to submit a supplemental application. The rule prescribes the timeframe within which the manufacturer shall maintain records that would enable it to take corrective action. The rule requires the manufacturer to submit lists pertaining to the disseminated articles and reference publications and the categories of persons (or individuals) receiving the information, and to submit a notice and summary of any additional research or data (and a copy of the data) relating to the product's safety or effectiveness for the new use. The rule requires the manufacturer to maintain a copy of the information, lists, records, and reports for 3 years after it has ceased dissemination of the information and to make the documents available to FDA for inspection and copying.

FDA based its estimates of the number of submissions it would receive and the number of manufacturers who would take advantage of part 99 on the number of efficacy and new use supplements for approved drugs, biologics, and devices received in fiscal year (FY) 1997 and on a projected increase in supplements due to FDAMA. In FY 1997, FDA received 198 efficacy and new use supplements from 115 manufacturers. The number of supplements increased 100 percent from FY 1995 to FY 1997 as a result of two new initiatives, the Prescription Drug User Fee Act and a new pediatric labeling regulation. If FDAMA results in an additional 50 percent increase in the number of supplements and a corresponding increase in the number of manufacturers, then the estimated number of submissions under part 99 is 297 (198 + (0.5 x 198)), and the estimated number of manufacturers is 172 (115 + (0.5 x 115)). These figures are reflected in tables 1 and 2 of this document for §§ 99.201(a)(1), 99.201(a)(2), 99.201(a)(3), 99.201(b), 99.201(c), 99.501(a)(1), 99.501(a)(2), 99.501(b)(1), 99.501(b)(3), and 99.501(c).

The estimated burden hours for these provisions are as follows:

Section 99.201(a)(1) requires the manufacturer to provide an identical copy of the information to be disseminated, including any required information. Because the manufacturer must compile this information in order to prepare its submission to FDA, FDA estimates that 40 hours would be required per submission. Because 297 annual responses are expected under § 99.201(a)(1), the total burden for this provision is 11,880 hours (297 responses x 40 hours per response).

Section 99.201(a)(2) requires the manufacturer to submit clinical trial information pertaining to the safety and effectiveness of the new use, clinical experience reports on the safety of the new use, and a summary of the information. FDA estimates 24 burden hours per response for this provision for assembling, reviewing, and submitting the information and assumes that the manufacturer will have already acquired some of this information in order to decide whether to disseminate information on an unapproved use under part 99. The total burden for this provision is 7,128 hours (297 annual responses x 24 hours per response).

Section 99.201(a)(3) requires the manufacturer to explain its search strategy when assembling its bibliography, and so FDA estimates that only 1 hour would be required for the explanation because the manufacturer would have developed and used its search strategy before preparing the bibliography. Because 297 annual responses are expected under § 99.201(a)(3), the total burden for this provision is 297 hours (297 annual responses x 1 hour per response).

Section 99.201(b) simply requires the manufacturer's attorney, agent, or other authorized official to sign its submissions, and certifications, or requests for an exemption. FDA, therefore, estimates that only 30 minutes are necessary for such signatures. Because 297 annual responses are expected under § 99.201(b), the total burden for this provision is 148.5 hours (297 response x 0.5 hours per response =148.5 hours).

Section 99.201(c) requires the manufacturer to provide two copies with its original submission. Copying the submission should not be time-consuming, so FDA estimates the burden to be 30 minutes. Because 297 annual responses are expected under § 99.201(c), the total burden for this provision is 148.5 hours.

While the act requires manufacturers to provide a submission to FDA before they disseminate information on unapproved/new uses, it also permits manufacturers to: (1) Have completed studies and promise to submit a supplemental application for the new use within 6 months of the date of initial dissemination; (2) provide protocols and a schedule for completing studies and submitting a supplemental application for the new use within 36 months of the date of initial dissemination; (3) have completed studies and have submitted a supplemental application for the new use; or (4) request an exemption from the requirement to submit a supplemental application. These possible scenarios are addressed in §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), 99.201(a)(5), and 99.205(b) respectively.

To determine the number of responses in §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), 99.201(a)(5), and 99.205(b), FDA began by estimating the

number of requests for an exemption under § 99.205(b). The legislative history indicates that such exemptions are to be limited. In the final rule, FDA estimated that approximately 10 percent of all respondents would seek--or 10 percent of all submissions would contain--an ''economically prohibitive'' exemption (resulting in 17 total respondents and approximately 30 annual responses) and that the estimated reporting burden per response would be 82 hours. This results in a total hour burden of 2,460 hours for § 99.205(b) (30 submissions x 82 hours per submission).

The estimated increase in the number of exemption requests results in a corresponding decrease in the remaining number of respondents and submissions under §§ 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), and 99.201(a)(5). FDA assumes that the remaining 267 submissions (297 total submissions - 30 submissions containing an exemption request) will be divided equally among § 99.201(a)(4)(i)(A), 99.201(a)(4)(ii)(A), and 99.201(a)(5), resulting in 89 responses in each provision (267 submissions/3 provisions). FDA has estimated the number of respondents in a similar fashion ((172 total respondents - 17 respondents submitting an exemption request)/3 provisions = 51.6, rounded up to 52 respondents per provision).

As stated earlier, § 99.201(a)(4)(i)(A)) requires the manufacturer, if the manufacturer has completed studies needed for the submission of a supplemental application for the new use, to submit the protocol(s) for the completed studies, or, if the protocol was submitted to an investigational new drug application (IND) or investigational device exemption (IDE), to submit the IND or IDE number(s), the date of submission of the protocol(s), the protocol number(s), and the date of any amendments to the protocol(s). FDA estimates that 30 hours would be required for this response because this is information that each manufacturer already maintains for its drugs or devices. The total burden for this provision is 2,670 hours (89 annual responses x 30 hours per response).

For manufacturers who submit protocols and a schedule for conducting studies, § 99.201(a)(4)(ii)(A)) requires the manufacturer to include, in its schedule, the projected dates on which the manufacturer expects the principal study events to occur. FDA estimates a manufacturer would need approximately 60 hours to include the projected dates because it would have to contact the studies' principal investigator(s) and other company officials. The total burden for this provision is 5,340 hours (89 annual responses x 60 hours per response).

If the manufacturer has submitted a supplemental application for the new use, § 99.201(a)(5) requires a cross-reference to that supplemental application. FDA estimates that only 1 hour would be needed because manufacturers already maintain this information. The total burden for this provision is 89 hours (89 annual responses x 1 hour per response).

Under § 99.203, a manufacturer who has certified that it will complete studies necessary to submit a supplemental application within 36 months after its submission to FDA, but later finds that it will be unable to complete such studies or submit a supplemental application within that time period, may request an extension of time from FDA. Such requests for extension should be limited, occurring less than 1 percent of the time, because manufacturers and FDA, when developing or reviewing study protocols, should be able to identify when a study will require more than 36 months to complete. Section 99.203 contemplates extension requests under two different scenarios. Under § 99.203(a), a manufacturer may make an extension request before it makes a submission to FDA regarding the dissemination of information under part 99. The agency expects such requests to be limited, occurring less than 1 percent of the time (or 1 annual response), and that such requests will result in a reporting burden of 10 hours per request. The total burden hours for this provision, therefore, is 10 hours (1 annual response x 10 hours per response).

Section 99.203(b) specifies the contents of a request to extend the time for completing planned studies after the manufacturer has provided its submission to FDA. The required information includes a description of the studies, the current status of the studies, reasons why the study cannot be completed on time, and an estimate of the additional time needed. FDA estimates that 10 hours for reporting the required information under § 99.203(b) because it would require consultation between the manufacturer and key individuals (such as the study's principal investigator(s)). As in the case of § 99.203(a), the expected number of responses is very small (one annual response), and the total burden hours for this provision is 10 hours (one annual response x 10 hours per response).

Section 99.203(c) requires two copies of an extension request (in addition to the request required under section 554(c)(3) of the act), and FDA estimates that these copies would result in a minimal reporting burden of 30 minutes. However, this requirement would apply to extension requests under §§ 99.203(a) and (b), so the total number of annual responses is two, resulting in a total burden hour for this provision of 1 hour (two annual responses x 0.5 hours per response).

The remaining reporting and recordkeeping burdens are as follows:

Section 99.501(a)(1) requires the manufacturer to maintain records that identify recipients by category or individually. Under § 99.301(a)(3), FDA will notify the manufacturer whether it needs to maintain records identifying individual recipients due to special safety considerations associated with the new use. This means that, in most cases, the manufacturer will only have to maintain records identifying recipients by category. In either event, the manufacturer will know whether it must maintain records that identify individual recipients before it begins disseminating information. The time required to identify recipients individually should be minimal, and the time required to identify recipients by category should be even less. Therefore, FDA estimates the burden for this provision to be 10 hours, and, because 297 annual responses are expected under § 99.501(a)(1), the total burden for this provision is 2,970 hours (297 annual responses x 10 hours per response).

Section 99.501(a)(2) requires the manufacturer to maintain a copy of the information it disseminates. This task is not expected to be time-consuming, so FDA estimates the burden to be 1 hour. Because 297 annual responses are expected under § 99.501(a)(2), the total burden for this provision is 297 hours (297 annual responses x 1 hour per response).

Section 99.501(b)(1) requires the manufacturer to submit to FDA semiannually a list containing the articles and reference publications that were disseminated in the preceding 6–month period. FDA tentatively estimates a burden of 8 hours for this provision. The actual burden may be less if the manufacturer develops and updates the list while it disseminates articles and reference publications during the 6–month period (as opposed to generating a completely new list at the end of each 6–month period) and if the volume of disseminated materials is small. The total burden for this provision is 4,752 hours (297 responses submitted semiannually x 8 hours per response = 297 x 2 x 8 = 4,752 hours).

Section 553(a)(2) of the act requires manufacturers that disseminate information to submit to FDA semiannually a list that identifies the categories of providers who received the articles and reference publications. Section 99.501(b)(2) also requires the list to identify which category of recipients received each particular article or reference publication. If each of the 297 submissions under part 99 results in disseminated information, § 99.501(b)(2) would result in 594 lists (297 submissions x 2 submissions/year) identifying which category of recipients received each particular article or reference publication. The agency estimates the burden to be only 1 hour per response because this type of information is maintained as a usual and customary business practice, and the total burden for this provision is 594 hours (594 lists x 1 hour per list).

In relation to § 99.201(a)(2), § 99.501(b)(3) requires the manufacturer to provide, on a semiannual basis, a notice and summary of any additional clinical research or other data relating to the safety and effectiveness of the new use and, if it possesses such research or data, to provide a copy to FDA. This burden should not be as extensive as that in § 99.201(a)(2), so FDA estimates the burden to be 20 hours per response, for a total burden of 11,880 hours for this provision (297 annual responses submitted semiannually x 20 hours per response = 297 x 2 x 20 = 11,880 hours).

If a manufacturer discontinues or terminates a study before completing it, § 99.501(b)(4)) requires the manufacturer to state the reasons for discontinuing or terminating the study in its next progress report. Based on FDA's regulatory experience in monitoring studies to support supplemental applications, FDA estimates this would affect only 1 percent of all applications (297 x 0.01 = 2.97, rounded up to 3) and only 2 manufacturers (172 x 0.01 = 1.72, rounded up to 2). FDA estimates 2 hours of reporting time for this requirement because the manufacturer should know the reasons for discontinuing or terminating the study and would only need to provide those reasons in its progress report. The total burden hours for this provision is 6 hours (three annual responses x 2 hours per response).

Section 99.501(b)(5) requires the manufacturer to submit any new or additional information that relates to whether the manufacturer continues to meet the requirements for the exemption after an exemption has been granted. FDA cannot determine, at this time, how many exemption requests will be granted, but, for purposes of this information collection, has estimated that 10 percent of all submissions will contain an exemption request (297 total submissions x 0.10 = 29.7, rounded up to 30) and has assumed that all exemption requests will be granted, for a total of 30 annual responses. The information sought under § 99.501(b)(5) pertains solely to new or additional information and is not expected to be as extensive as the information required to obtain an exemption.

Thus, FDA tentatively estimates the burden for § 99.501(b)(5) to be 41 hours per response (or half the burden associated with an exemption request), for a total burden of 1,230 hours for this provision (30 annual responses x 41 hours per response).

Section 99.501(c) requires the manufacturer to maintain records for 3 years after it has ceased dissemination of the information. FDA estimates the burden hour for this provision to be 1 hour. Because 297 annual responses are expected under § 99.501(c), the total burden for this provision is 297 hours.

Description of Respondents: All manufacturers (persons and businesses, including small businesses) of drugs, biologics, and device products.

In the **Federal Register** of April 16, 2002 (67 FR 18626), FDA invited comments on the collection of information. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
99.201(a)(1)	172	1.7	297	40	11,880
99.201(a)(2)	172	1.7	297	24	7,128
99.201(a)(3)	172	1.7	297	1	297
99.201(a)(4)(i)(A)	52	1.7	89	30	2,670
99.201(a)(4)(ii)(A)	52	1.7	89	60	5,340
99.201(a)(5)	52	1.7	89	1	89
99.201(b)	172	1.7	297	0.5	148.5
99.201(c)	172	1.7	297	0.5	148.5
99.203(a)	1	1	1	10	10
99.203(b)	1	1	1	10	10
99.203(c)	2	1	2	0.5	1
99.205(b)	17	1.8	30	82	2,460
99.501(b)(1)	172	3.4	594	8	4,752
99.501(b)(2)	172	3.4	594	1	594
99.501(b)(3)	172	3.4	594	20	11,880

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]

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; 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