agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Seleda Perryman, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice. Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Projects

1. Requirement for a Special Permit to Import Cynomolgus-African Green or Rhesus Monkeys—(0920–0263)—Extension—National Center for Infectious Disease (NCID) Division of Quarantine—A registered importer nonhuman primates must submit to the Director, CDC, a written plan which specifies the steps that will be taken to prevent exposure of persons and animals during the entire importation and quarantine process for the arriving nonhuman primates. Under the special permit arrangement, registered importers must submit a plan to CDC for the importation and quarantine if they wish to import the specific monkeys covered. The plan must address disease prevention procedures to be carried out in every step of the chain of custody of such monkeys, from embarkation in the country of origin to release from quarantine. Information such as species, origin and intended use for monkeys, transit information, isolation and quarantine procedures, and procedures for testing of quarantined animals is necessary for CDC to make public health decisions. This information enables CDC to evaluate compliance with the standards and determine whether the measures being taken to prevent exposure of persons and animals during importation are adequate. Once CDC is assured, through the monitoring of shipments (normally no more than 2), that the provisions of a special permit plan are being followed by a new permit holder, and that the use of adequate disease control practices is being demonstrated, the special permit is extended to cover the receipt of additional shipments under the same plan for a period of 180 days, and may be renewed upon request. This eliminates the burden on importers to repeatedly report identical information, requiring only that specific shipment itineraries and information on changes to the plan which require approval be submitted.

The respondents are commercial or not-for-profit importers of nonhuman primates. We are requesting clearance for 3 years. Total cost to Respondents: $350 (14 x $25)

Respondents	Number of respondents	Number of responses/respondent	Avg. burden/response (in hrs.)	Total burden (in hrs.)
Businesses	5	5	2@0.5; 3@0.1	6.5
Organizations	15	5	0.1	7.5
Total				14

Dated: July 29, 1998.

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–20719 Filed 8–3–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0453]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection and information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the submission of applications to recognized accreditation bodies that will assess potential U.S. Conformity Assessment Bodies (CAB's) seeking to be designated under the United States (U.S.)/European Community (EC) Mutual Recognition Agreement (MRA) to assess medical devices produced for the EC market. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing OMB's approval of this collection of information (OMB control number 0910–0378). Since this was an emergency approval that expires on January 31, 1999, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written comments on the collection of information by October 5, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Medical Devices: Third-Party Review Program Under U.S./EC MRA (OMB Control Number 0910–0378—Extension)

The third-party program under U.S./EC MRA is intended to implement that part of U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under MRA, firms may apply to become designated as a U.S. CAB. Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product-type examinations and verifications for selected devices based on EC requirements under the voluntary third-party program authorized by MRA. Firms designated as EC CAB's could, in turn, conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by EC CAB's to FDA. EC CAB's would also be required to maintain copies of their evaluation reports.

FDA estimates the burden of this collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	Number of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Requests for Designation as U.S. CAB	12	1	12	24	288
Premarket Reports by EC CAB's	20	5	100	40	4,000
Quality System Reports by EC CAB's	20	5	100	32	3,200
Total					7,488

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Records of Evaluation of Premarket Submissions by EC CAB's	20	5	100	10	1,000
Records of Evaluation of Quality Systems	20	5	100	10	1,000
Total					2,000

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

The burdens are explained as follows:

I. Reporting

A. Requests for Designation as U.S. CAB

Under this program, U.S. firms may apply for designation as a U.S. CAB. Such designation will enable that firm to perform third-party evaluations of U.S. products for export to EC. Likewise, European firms may apply to be designated as EC CAB's, which will enable them to perform third-party evaluations of products to be exported to the United States. The application for nomination as an EC CAB does not represent a paperwork burden subject to the PRA because the designation procedure is an internal process which is required by, and administered by, European authorities. Only the application for designation as a U.S. CAB represents a paperwork burden under the PRA. The agency anticipates, based on discussions with the National Institute of Science and Technology of the U.S. Department of Commerce and officials of other standards organizations, that approximately 12 applications for designation as U.S. CAB's will be received.

B. Premarket Reports

Under this program, EC CAB's will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EC CAB's would be required to submit reports of their evaluations to FDA. Based upon information gathered during the negotiation of U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluation for approximately 100 medical device products annually. The agency further estimates, based on dialogue with EC officials, that 20 firms will be designated to act as EC CAB's.

C. Quality System Reports

Under this program, EC CAB's will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EC CAB's would be required to submit reports of their evaluations to FDA. Based upon information gathered during the negotiation of U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluations for approximately 100 medical device products annually. The agency estimates that 20 EC CAB's will perform these evaluations.

II. Recordkeeping

As stated previously, firms designated as EC CAB's will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such evaluation will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each evaluation. The agency anticipates that 100 premarket

reports and 100 quality system reports will be generated and required to be maintained by EC CAB's annually. Thus, the agency estimates that 100 records of evaluations of quality systems and premarket submissions will be retained by the designated EC CAB's. Based on experience with the Third-Party Review Pilot Program, which was announced in the **Federal Register** of April 3, 1996 (61 FR 14789), the agency anticipates that each recordkeeper will require no more than 2 hours of recordkeeping per review. The agency is estimating 5 reviews per respondent and a total of 10 hours per recordkeeper.

Dated: July 24, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–20702 Filed 8–3–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0331]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the Third–Party Review Pilot Program established by FDA's Center for Devices and Radiological Health (CDRH) under the FDA Modernization Act of 1997 (FDAMA). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing OMB's approval of this collection of information (OMB control number 0910–0375). Since this was an emergency approval that expires on November 30, 1998, FDA is following the normal PRA clearance procedures by isuing this notice.

DATES: Submit written comments on the collection of information by October 5, 1998.

ADDRESSES: Submit written comments on the collection of information to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506 (c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth below.

With respect to the following collection of information, FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Medical Devices; FDAMA Third–Party Review (OMB Control Number 0910–0375—Extension)

Description: Section 210 of FDAMA establishes a new section 523 of the Federal Food, Drug, and Cosmetic Act (the act), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the Third–Party Review Pilot Program previously conducted by FDA, participation in this Third–Party Review Pilot Program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation. Accredited third-party reviewers will have the ability to review a manufacturer's 510(k) submission for selected devices. After reviewing a submission, the reviewer will forward a copy of the 510(k) submission, along with the reviewer's documented review and recommendation, to FDA. Third-party reviewers should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time. This information collection will allow FDA to implement the Accredited Person Review Program established by FDAMA and improve the efficiency of 510(k) review for low to moderate-risk devices.

Description of Respondents: Businesses or other for profit organizations.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Item	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Hours per Respondent	Total Hours
Requests for accreditation	40	1	40	24	960
510(k) reviews conducted by accredited third parties	35	4	140	40	5,600
Total hours					6,560

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