DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0437]

Agency Information Collection Activities; Proposed Collection; Comment Request; Medical Devices; Third-Party Review Under the Food and Drug Administration Modernization Act, Third-Party Premarket Submission Review, and Quality System Inspections Under the United States/European Community Mutual Recognition Agreement

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 information collection, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection requirements for medical devices; third-party review under the Food and Drug Administration Modernization Act (FDAMA), third-party premarket submission review, and quality system inspections under the United States/European Community (U.S./E.C.) Mutual Recognition Agreement (MRA).

DATES: Submit written and electronic comments on the collection of information by [*insert date 60 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (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: Peggy Robbins, Office of Management Programs (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 in this document.

With respect to the following collection of information, FDA invites comments on these topics: (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 Under FDAMA, Third-Party Premarket Submission Review, and Quality System Inspections Under U.S./ E.C. Mutual Recognition Agreement (OMB Control Number 0910–0378)—Extension

Section 210 of FDAMA established section 523 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. Participation in this third party review program by accredited persons is entirely voluntary. A third party wishing to participate will submit a request for accreditation to FDA. Accredited third-party reviewers have the ability to review a manufacturer's submission under section 510(k) of the act (21 U.S.C. 360(k)) 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 reviews should maintain records of their 510(k) reviews and a copy of the 510(k) for a reasonable period of time, usually a period of 3 years. This information collection will allow FDA to continue to implement the accredited person

review program established by FDAMA and improve the efficiency of 510(k) review for low-to-moderate risk devices.

The third-party program under the U.S/E.C. MRA is intended to implement that part of the U.S./E.C. 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 the MRA, firms may apply to become designated as a U.S. conformity assessment body (CAB). Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product type evaluations and verifications for selected devices based on European Union (EU) requirements under the voluntary third-party program authorized by MRA. Firms designated as EU CABs could conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA's requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by the EU CABs to FDA. The EU CABs would also be required to maintain copies of their evaluation reports for a period of no less than 3 years.

Respondents to this information collection are 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	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for accreditation	15	1	15	24	360
510(k) reviews conducted by accredited third parties	15	14	210	40	8,400
Premarket reports by EU CABs	9	5	45	40	1,800
Quality system reports by EU CABs	9	4	36	32	1,152
Totals					11,712

[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 Record-keepers	Annual Frequency per Recordkeeper	Total Annual Records	Hours per Record-keeper	Total Hours
510(k) reviews	15	14	210	10	2,100
Premarket reports by EU CABs	9	5	45	10	450
Quality system reports by EU CABs	9	4	36	10	360
Totals					2,910

[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 Accreditation

Under the agency's third-party review pilot program, the agency received 37 applications for recognition as third-party reviewers, of which the agency recognized 7. In the past 3 years, however, the agency has averaged receipt of 15 applications for recognition of third-party review accredited persons, and 9 EU CABS. The agency has accredited 15 of the applicants to conduct third-party reviews, and 9 EU CABs.

B. 510(k) Reviews Conducted by Accredited Third Parties

In the 18 months under the third-party review pilot program, FDA received only 22 total 510(k)s that requested and were eligible for review by third parties. Because the third-party review program is not as limited in time as the pilot program, and is expanded in scope, the agency anticipates that the number of 510(k)s submitted for third-party review will remain the same as they were during the last OMB approval in 2001. The agency has experienced that the number of 510(k)s submitted by accredited persons for third-party review since the last OMB approval in 2001 has been approximately 210 annually, which is 14 annual reviews per each of the estimated 15 accredited reviewers.

1. Premarket Reports

Under this program, EU CABs will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered since this collection was last reviewed in 2001, the agency has experienced that nine European manufacturers have not received any third-party requests for review annually. The agency estimates, based on dialog with EU officials and actual experience, nine firms will be designated to act as EU CABs.

2. Quality System Reports

Under this program, EU CABs 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. EU CABs would be required to submit to FDA reports of their evaluations. Based upon information gathered during the negotiation of the U.S./E.C. MRA and actual experience since the collection was last approved by OMB in 2001, the agency anticipates that European manufacturers will request third-party audits for approximately 36 medical device products annually. The agency estimates that 9 EU CABs will perform these evaluations.

II. Recordkeeping

Third-party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 210 annual submissions of 510(k)s for third-party review.

As stated previously, firms designated as EU CABs 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 review 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 review. The agency anticipates that 45 premarket reports and 36 quality system reports will be generated and required to be maintained by EU CABs annually. The agency further estimates that each

reviewer will require no more than 10 hours (2 hours per recordkeeping per report) for each to maintain such records annually.

Dated: October 4, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–????? Filed ??–??–04; 8:45 am]

BILLING CODE 4160–01–S