an entry on the World Wide Web for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. Updated on a regular basis, the CDRH Home Page includes the ''Draft Guidance for Staff, Industry and Third Parties: Third Party Programs Under the Sectoral Annex on Medical Devices to the Agreement on Mutual Recognition Between the United States of America and the European Community (MRA),'' device safety alerts, access to **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.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185. The terminal settings are 8/1/N. After the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA Home Page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

IV. Comments

Interested persons may, on or before (*insert date 30 days after publication in the* **Federal Register**), submit to Dockets Management Branch (address above) written comments regarding this draft guidance.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 document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17600 Filed 7–1–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0453]

Agency Emergency Processing Under OMB Review

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). The proposed collection of information concerns 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 U.S./European Community (EC) Mutual Recognition Agreement (MRA) to assess medical devices produced for the EC market. This collection of information also concerns the submission of third-party evaluation reports by EC CAB's under the program. FDA is requesting OMB approval within 15 days of receipt of this submission.

DATES: Submit written comments on the collection of information by July 13, 1998.

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: Desk Officer for FDA. 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:

I. Background

FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA and 5 CFR 1320.13. The information is needed immediately in order for potential CAB's to be designated in time to participate in training for premarket and quality systems evaluations scheduled for October 14 through 23, 1998. The use of normal clearance procedures would be likely to result in the prevention or disruption of this collection of information and would delay the implementation of the confidence building activities authorized by the U.S./EC MRA.

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.

The third-party program under the U.S./EC MRA is intended to implement that part of the 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 the 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 the 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 the EC CAB's to FDA. The 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	Annual Frequency per Response	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:

II. 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 the 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 to FDA reports of their evaluations. Based upon information gathered during the negotiation of the 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 to FDA reports of their evaluations. Based upon information gathered during the negotiation of the 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.

III. 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; therefore, the total number of hours per recordkeeper is 10.

Dated: June 24, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–17602 Filed 7–1–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Nonvoting Representatives of Consumer and Industry Interests on Public Advisory Panels or Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for nonvoting consumer representatives and nonvoting industry representatives to serve on certain device panels of the Medical Devices Advisory Committee in the Center for Devices and Radiological Health (CDRH). Nominations will be accepted for current vacancies and for those that will or may occur through June 30, 1999.

FDA has a special interest in ensuring that women, minority groups, individuals with disabilities, and small businesses are adequately represented on advisory committees and, therefore,