Dated: May 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Medical Devices; Implementation of Third Party Review Under the Food and Drug Administration Modernization Act of 1997; Emergency Processing Request Under OMB Review

[Docket No. 98N–0331]

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a program under which persons may be accredited to review premarket notifications and recommend initial classification of certain medical devices. At the same time, FDA is announcing the termination of the Third Party Review Pilot Program. This notice announces the criteria to accredit or deny accreditation to persons (Accredited Persons) who request to conduct premarket notification reviews consistent with provisions of the FDA Modernization Act of 1997 (FDAMA). FDA is also announcing that this 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). FDA is requesting OMB approval within 45 days of receipt of this submission. FDA is taking this action to implement section 210 of FDAMA. The availability of guidance detailing the review of submissions, training for third party reviewers, and basic document processing by FDA is announced elsewhere in this issue of the **Federal Register**.

DATES: Submit written comments on the collection of information by June 22, 1998. FDA will begin accepting applications for accreditation of Accredited Persons on July 20, 1998, and intends to make a list of Accredited Persons available on or about September 23, 1998. Beginning November 21, 1998, the agency will accept reviews and recommendations from Accredited Persons. On that same date, FDA plans to terminate the Third Party Review Pilot Program that began on August 1, 1996. FDA is currently planning to provide periodic training sessions for Accredited Persons, with the first such session scheduled for October 14-16, 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: John F. Stigi, Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–443–6597, FAX 301–443–8818.

SUPPLEMENTARY INFORMATION:

I. Background

A. Third Party Review Pilot Program

In the **Federal Register** of April 3, 1996 (61 FR 14789), FDA announced that it would begin a 2-year voluntary pilot program to test the feasibility of using third party reviewers to improve the efficiency of the agency's review of 510(k)'s for selected low-and-moderate risk medical devices. FDA had previously solicited public comments on its plans for the pilot program in a notice issued in the **Federal Register** of June 1, 1995 (60 FR 28618), and at a public workshop held June 19, 1995. The comments received by the agency were addressed in the **Federal Register** notice (61 FR 14789).

The program announced in the April 3, 1996, notice provided for third party review for 251 types of devices that were included in the pilot program. These included all class I devices that were not exempt from 510(k) at that time (221 devices), and 30 class II devices, 24 of which were to be phased into the program over time.

Under the pilot program, persons required to submit 510(k)'s for the eligible devices were permitted to contract with an FDA Recognized Third Party and submit a 510(k) directly to the third party for review. Persons who did not wish to participate in the pilot continued to submit 510(k)'s directly to FDA. The third party applied FDA's 510(k) review criteria and submitted its documented review and recommendation on the substantial equivalence of the device to FDA. FDA then checked the review and issued a decision letter. FDA established a 30-day performance goal for its issuance of final decisions based on third party reviews.

The purpose of the pilot program was to: (1) Provide manufacturers of eligible devices with an alternative review process that could yield more rapid marketing clearance decisions, and (2) enable FDA to target its scientific review resources at higher-risk devices while maintaining confidence in the review by third parties of low-to-moderate risk devices. The pilot program was intended to determine the feasibility of these outcomes.

The agency received applications for recognition as third party reviewers from 37 prospective third parties. These applications were reviewed by a Third Party Recognition Board established by FDA. On July 11, 1996, FDA made publicly available a list of seven Recognized Third Parties, and immediately began a training program for third party review.

The pilot program began August 1, 1996, as scheduled. During the first 18 months of the pilot program, FDA received 22 510(k)'s that were reviewed by Recognized Third Parties. In contrast, during the same period, FDA received more than 1,300 510(k)'s for third party-eligible devices that were not reviewed by third parties.

B. FDA Modernization Act of 1997

The President signed FDAMA into law on November 21, 1997. Section 210 of FDAMA codifies and expands the ongoing Third Party Review Pilot Program by establishing a new section 523 of Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360m), directing FDA to accredit persons in the private sector to conduct the initial review of 510(k)'s for selected low-to-moderate risk devices. This section specifies that an Accredited Person may not review class III devices or class II devices that are permanently implantable, life-supporting, life-sustaining, or for which clinical data are required. This section also sets limits on the number of class II devices requiring clinical data that may be ineligible for Accredited Person review.

II. FDAMA Third Party Review Program

Under the provisions of FDAMA, FDA is establishing the criteria it will use to determine whether it will accredit or deny accreditation of persons for the purpose of reviewing reports submitted under section 510(k) of the act (21 U.S.C. 360(k)) and making recommendations to FDA regarding the initial classification of devices under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)). As intended by Congress,

this process is an expansion of FDA's Third Party Review Pilot Program. This expanded program is applicable to a greater number and variety of devices. To ensure accurate and timely review, Accredited Persons will be expected to consult review guidance or national and/or international standards recognized by FDA. FDA is making available on the CDRH home page on the World Wide Web a list of devices for which there are recognized standards or review guidance and which will be eligible for review by Accredited Persons. FDA will update the list regularly.

To be accredited by FDA, applicants must demonstrate that they have the appropriate qualifications and facilities to conduct competent 510(k) reviews and have instituted effective controls to prevent any conflict of interest or appearance of conflict of interest that might affect the review process.

In accordance with FDAMA, to be accredited by FDA an applicant must, at a minimum, have the following qualifications:

(1) An Accredited Person may not be a Federal Government employee;

(2) An Accredited Person shall be an independent organization not owned or controlled by a manufacturer, supplier, or vendor of devices and have no organizational, material, or financial affiliation with such a manufacturer, supplier, or vendor;

(3) An Accredited Person shall be a legally constituted entity permitted to conduct the activities for which it seeks accreditation;

(4) An Accredited Person shall not engage in the design, manufacture, promotion, or sale of devices;

(5) An Accredited Person shall operate in accordance with generally accepted professional and ethical business practices and agree in writing that, at a minimum, it will:

(a) Certify that reported information accurately reflects data reviewed;

(b) Limit work to that for which competence and capacity are available;

(c) Treat information received, records, reports, and recommendations as proprietary information;

(d) Promptly respond and attempt to resolve complaints regarding its activities for which it is accredited; and

(e) Protect against the use of any officer or employee of the Accredited Person who has a financial conflict of interest regarding the device, and annually make available to the public disclosures of the extent to which the Accredited Person, and the officers and employees of the Accredited Person, have maintained compliance with requirements relating to financial conflicts of interest.

In accordance with FDAMA, an Accredited Person also must, at a minimum, maintain records that support its initial and continuing qualifications to be an Accredited Person. These records include:

(1) Documenting the training qualifications of the Accredited Person and the employees of the Accredited Person;

(2) The procedures used by the Accredited Person for handling confidential information;

(3) The compensation arrangements made by the Accredited Person; and

(4) The procedures used by the Accredited Person to identify and avoid conflicts of interest.

In addition to the above minimum requirements for Accredited Persons, FDA is establishing the following:

1. Personnel Qualifications

FDA expects to consider several factors with respect to personnel qualifications when it considers accrediting applicants. These include:

(1) Whether the applicant's personnel have demonstrated knowledge of:

- The Federal Food, Drug, and Cosmetic Act (21 U.S.C., 301 *et seq.*);
- The Public Health Service Act (42 U.S.C., 201 *et seq.*); and
- The regulations implementing these statutes, particularly 21 CFR parts 800 through 1299.

(2) Whether the applicant:

- Has established, documented, and executed policies and procedures to ensure that 510(k)'s are reviewed by qualified personnel, and will maintain records on the relevant education, training, skills, and experience of all personnel who contribute to the technical review of a 510(k);
- Has clear written instructions for duties and responsibilities with respect to 510(k) reviews available to its personnel;
- Has employed personnel who, as a whole, are qualified in all of the scientific disciplines addressed by the 510(k)'s that the Accredited Person accepts for review;
- Has identified at least one individual who is responsible for providing supervision over 510(k) reviews and who has sufficient authority and competence to assess the quality and acceptability of these reviews; and
- Is prepared to conduct technically competent reviews at the time of requesting accreditation by FDA.

(3) For appropriate review of a particular class II device, FDA will expect specialized education or experience to assure a technically competent review. In addition, Accredited Persons will be expected to consult national and/or international standards recognized by FDA or review guidance.

2. Facilities

FDA expects to accredit persons that have the capability to interface with FDA's electronic data systems, including FDA home page, CDRH home page, and CDRH Facts-On-Demand. At a minimum, this would include a computer system with a modem and an independent facsimile machine. FDA will rely extensively on the use of FDA's electronic data systems for timely public dissemination of guidance documents to Accredited Persons.

3. Prevention of Conflicts of Interest

FDA expects Accredited Persons to be impartial and free from any commercial, financial, and other pressures that might present a conflict of interest or an appearance of conflict of interest. To that end, when deciding whether to accredit a person, FDA will consider whether the person has established, documented, and executed policies and procedures to prevent any individual or organizational conflict of interest, including conflicts of contractors or individual contract employees.

4. Training

Accredited Persons must certify in their application that they will have designated employees attend FDA training for Accredited Persons. FDA plans to provide such training on a periodic basis for persons newly accredited. FDA encourages applicants who wish to begin submitting reviews on November 21, 1998, to apply at least 60 days before the scheduled October 14 through 16, 1998 training session. FDA will not accept 510(k) reviews and recommendations from Accredited Persons that have failed to have at least one designated employee attend a training session for Accredited Persons.

C. Safeguards

The Third Party Review Program established by FDAMA includes safeguards to maintain a high level of quality in 510(k)'s reviewed by Accredited Persons and to minimize risk to public health. To ensure that persons accredited under section 523 of the act will continue to meet the standards of accreditation, the statute requires FDA to: (1) Make onsite visits on a periodic basis to each Accredited Person to audit the performance of such person, and (2) take such additional

measures as the agency determines to be appropriate.

In addition, the statute permits FDA to suspend or withdraw accreditation of any person accredited under section 523 of the act, after providing notice and an opportunity for an informal hearing, when such person is substantially not in compliance with the requirements of this section or poses a threat to public health or fails to act in a manner consistent with the purposes of this section.

The act also has been amended to establish a new prohibited act section to protect the integrity of the Accredited Person Program established by section 523 of the act. It is a prohibited act under new section 301(y)(1) of the act (21 U.S.C. 331(y)(1)) for an Accredited Person to:

(1) Submit a report that is false or misleading in any material respect;

(2) Disclose confidential information or trade secrets without the express written consent of the person who submitted such information or secrets to the Accredited Person; or

(3) Receive a bribe in any form or do a corrupt act associated with a responsibility delegated to the Accredited Person under the act.

FDA also is requiring applicants who wish to become an Accredited Person to establish policies designed to identify, prevent, and ensure reporting to FDA, of instances of forum shopping by submitters of 510(k)'s. Submitters of 510(k)'s who consult with more than one party in order to find the Accredited Person who is most likely to recommend clearance of the 510(k) will undermine the independence and integrity of the Accredited Person Review Program. FDA, therefore, expects Accredited Persons to ensure that the submitters of the 510(k)'s they are reviewing have not previously presented the submission to another Accredited Person.

It is not feasible to identify or state categorically all of the criteria for evaluating whether a submitter has forum shopped. However, if FDA determines that a submitter has obtained reviews of the same 510(k) from more than one Accredited Person, there will be a presumption of forum shopping and FDA may refuse to provide special processing of a submitter's 510(k) unless the submitter can explain to FDA's satisfaction why the circumstances do not indicate forum shopping.

III. Environmental Impact

The agency has determined under 21 CFR 25.30(k) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Paperwork Reduction Act of 1995

This voluntary third party review program contains information collection provisions which 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). FDA has submitted this proposed collection of information to OMB and has requested emergency processing under section 3507(j) of the Paperwork Reduction Act of 1995 and 5 CFR 1320.13. The information is essential to the agency's mission and is needed immediately to meet the statutory deadline for implementation of the voluntary third party review program as required by FDAMA. The use of normal clearance procedures would be likely to result in the prevention or disruption of this collection of information. The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual recordkeeping and periodic reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing each collection of information.

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.

Description: Section 210 of FDAMA establishes a new section 523 of the act, directing FDA to accredit persons in the private sector to review certain premarket applications and notifications. As with the third party pilot program previously conducted by FDA, 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. 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 Respondents	Total Annual Responses	Hours per Respondents	Total Hours
Request for accreditation	40	1	40	24	960
510(k) reviews conducted by accredited 3rd 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.

TABLE 2.—Estimated Annual Recordkeeping Burden[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
510(k) reviews	35	4	140	60	8,400

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

The burdens are explained as follows:

1. 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. Under this expanded program, the agency anticipates that it will not see a significant increase in the number of applicants. Therefore, the agency is estimating that it will receive 40 applications. The agency anticipates that it will accredit 35 of the applicants to conduct third-party reviews.

b. *510(k) reviews conducted by accredited third-parties:* In 18 months under the Third Party Review Pilot Program, FDA received only 22 510(k)'s that requested and were eligible for review by third parties. Because the new program is not as limited in time, and is expanded in scope, the agency anticipates that the number of 510(k)'s submitted for third-party review will increase. The agency anticipates that it will receive approximately 140 third party review submissions annually, i.e., approximately 4 annual reviews per each of the estimated 35 accredited reviewers.

2. Recordkeeping

Third party reviewers are required to keep records of their review of each submission. The agency anticipates approximately 140 annual submissions of 510(k)'s for third party review.

Prior to the implementation of the program, FDA will publish in the **Federal Register** a notice of OMB's decision to approve, modify, or disapprove the information collection provisions. 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.

Dated: May 19, 1998.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 98–13799 Filed 5–20–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0438]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''User Fee Cover Sheet'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 13, 1998 (63 FR 7420), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0297. The approval expires on April 30, 2001.

Dated: May 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13648 Filed 5–21–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0327]

Agency Information Collection Activities; Announcement of OMB Approval

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a collection of information entitled ''Petition for Administrative Stay of Action'' has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA).

FOR FURTHER INFORMATION CONTACT: JonnaLynn P. Capezzuto, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of February 12, 1998 (63 FR 7173 and 7174), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under section 3507 of the PRA (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 0910–0194. The approval expires on April 30, 2001.

Dated: May 14, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–13649 Filed 5–21–98; 8:45 am]

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