

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003N-0066]

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices Inspection by Accredited Persons Program Under MDUFMA (OMB Control Number 0910-0510)—Extension

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) was signed into law on October 26, 2002. Section 201 of MDUFMA adds a new paragraph “g” to section 704 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 374), directing FDA to accredit third parties (accredited persons or APs) to conduct inspections of eligible manufacturers of class II or class III devices. This is a voluntary program; eligible manufacturers have the option of being inspected by an AP or by FDA. The new law requires FDA, within 180 days from the date of MDUFMA was signed into law, to publish in the **Federal Register** criteria to accredit or deny accreditation to persons who request to perform these inspections (section 704(g)(2) of the act).

In the **Federal Register** of April 28, 2003 (68 FR 22388), FDA published a notice announcing that a proposed collection of information has been submitted to OMB for emergency processing under the PRA. Interested persons were given until May 28, 2003, to comment on the notice. Elsewhere in the April 28, 2003, issue of the **Federal Register** (68 FR 22400), FDA published a document announcing the criteria it will use to accredit persons to inspect eligible device manufacturers and the availability of a guidance entitled “Implementation of the Inspection by Accredited Persons Program Under the Medical Device User Fee and Modernization Act of 2002; Accreditation Criteria: Guidance for Industry, FDA Staff, and Third Parties.”

FDA received a total of three comments from a trade association, an industry association, and a consultant. These comments were not specifically related to the information collection for the submission of applications to become an accredited person. The comments addressed the implementation of the third party inspection program. FDA will take these comments into consideration in further developing its third party inspection program.

Description of Respondents: Businesses or other for profit organizations.

In the **Federal Register** of July 10, 2003 (68 FR 41160), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Request for Accreditation (First Year)	25	1	25	80	2,000
Request for Accreditation (Second Year)	10	1	10	15	150
Request for Accreditation (Third Year)	5	1	5	80	400
Total					2,550

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

FDA based these estimates on conversations with industry, trade association representatives, and internal FDA estimates. Our expectation is that 25 bodies will apply and meet the minimum standard for being accredited. Under MDUFMA, we can only accredit 15 persons during the first year. We (FDA) expect that the lowest ranking, 10 (the ones not accredited), will reapply the following year and will submit an updated application. Five new applicants may apply the third year. Once an organization is accredited, it will not be required to reapply.

Dated: 9-30-03

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September 30, 2003.

Jeffrey Shuren

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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George