

following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection.

*Title of Information Collection:* Request for Reconsideration of Part A Medicare Claims and Supporting Regulations in 42 CFR, 405.711.

*Form No.:* CMS-2649 (OMB# 0938-0045).

*Use:* Section 1869 of the Social Security Act authorizes a hearing for any individual who is dissatisfied with the intermediary's determination or amount of benefit paid. This form is used so that a party may request a reconsideration of the initial determination.

*Frequency:* Monthly, Quarterly, Annually.

*Affected Public:* Individuals or Households and Not-for-profit institutions.

*Number of Respondents:* 60,000.

*Total Annual Responses:* 60,000.

*Total Annual Hours:* 15,000.

2. *Type of Information Collection Request:* Extension of a currently approved collection.

*Title of Information Collection:* Employee Building Pass Application and File.

*Form No.:* CMS-730 & CMS-80 (OMB# 0938-0812).

*Use:* The purpose of this system is to control United States Government Building Passes issued to all Centers for Medicare & Medicaid Services (CMS) employees and non-CMS employees who require continuous access to CMS buildings in Baltimore and other CMS and HHS Buildings.

*Frequency:* As needed.

*Affected Public:* Federal Government and Business or other for-profit.

*Number of Respondents:* 2000.

*Total Annual Responses:* 2000.

*Total Annual Hours:* 500.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site

address at <http://cms.hhs.gov/regulations/pr/default.asp>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@hcfa.gov](mailto:Paperwork@hcfa.gov), or call the Reports Clearance Office on (410) 786-1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: October 2, 2003.

**Dawn Willingham,**

*CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0311]

#### Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Device User Fee and Modernization Act Small Business Qualification Certification (Form FDA 3602)

**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.

**DATES:** Submit written comments on the collection of information by November 10, 2003.

**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.

#### MDUFMA Small Business Qualification Certification (Form FDA 3602)—(OMB Control Number 0910-0508)—Extension

Medical Device User Fee and Modernization Act (MDUFMA) amends the Federal Food, Drug, and Cosmetic Act to provide for user fees for certain medical device applications. The initial fees (for fiscal year (FY) 2003) are set by statute; FDA will publish a **Federal Register** notice by August 1, 2003, announcing the fees for FY 2004. To avoid harming small businesses, MDUFMA provides for reduced or waived fees for applicants who qualify as a "small business." This means there are two levels of fees, a standard fee, and a reduced or waived small business fee.

Presently, a "small business" is an applicant who reported no more than \$30 million "gross receipts or sales" on its Federal income tax return for the most recent tax year; the applicant must count the "gross receipts or sales" of all of its affiliates, partners, or parent firms when calculating whether it meets the \$30 million threshold. An applicant must pay the full standard fee unless it provides evidence demonstrating to FDA that it meets the "small business" criteria. The evidence required by MDUFMA is a copy of the most recent Federal income tax return of the applicant, and any affiliate, partner, or parent firm. FDA will review these materials and decide whether an applicant is a "small business" within the meaning of MDUFMA.

Form FDA 3602 will be available in a forthcoming guidance document, "MDUFMA Small Business Qualification Worksheet and Certification." This guidance will describe the criteria FDA will use to decide whether an entity qualifies as a MDUFMA small business and will help prospective applicants understand what they need to do to meet the small business criteria for FY 2004 and subsequent fiscal years. FDA will publish this guidance by August 1, 2003.

Respondents will be businesses or other for-profit organizations.

In the **Federal Register** of July 18, 2003 (68 FR 42742), 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 BURDEN<sup>1</sup>

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	3,000	1	3,000	1	3,000

<sup>1</sup>There 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 from internal FDA estimates. This represents FDA's estimate on the number of small businesses that will submit a premarket notification, a premarket application, a premarket report, a panel track supplement, efficacy supplement, 180-day supplement, or a real time supplement to FDA during a single fiscal year from FY 2004 through 2007.

Dated: October 6, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0016]

#### Agency Information Collection Activities; Announcement of Office of Management and Budget Approval; The FDA Medical Products Reporting Program

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a collection of information entitled "The FDA Medical Products Reporting Program" has been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In the **Federal Register** of April 29, 2003 (FR 68 22716), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 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 0910-0291.

As requested by the agency, in addition to the approval of the revised forms, the existing forms are approved for continued use for the next 6 months to allow for the industry to make necessary changes to their computerized systems. The approval expires on March 31, 2005. A copy of the supporting statement for this information collection is available on the Internet at <http://www.fda.gov/ohrms/dockets>.

Dated: October 6, 2003.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2003N-0456]

#### Agency Information Collection Activities; Proposed Collection; Comment Request; Prevention of Medical Gas Mixups at Health Care Facilities

**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on measures taken by certain Health Care medical facilities that use medical oxygen to prevent mixups with other gases.

**DATES:** Submit written or electronic comments on the collection of information by December 9, 2003.

**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:** Karen Nelson, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482

**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, 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,