

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 03N-0065]

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Agency Emergency Processing Under OMB Review; Fiscal Year 2003

MDUFMA 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 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 will permit an applicant to certify that it qualifies as a "small business" within the meaning of the Medical Device User Fee and Modernization Act (MDUFMA), will help the applicant organize the information FDA needs to verify each certification, and will collect contact information to facilitate rapid resolution of any questions FDA may have concerning information the applicant has provided.

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

ADDRESSES: Fax written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Attn: Stuart Shapiro, Desk Officer for FDA, FAX 202-395-6974, or electronically mail comments to sshapiro@omb.eop.gov. 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 Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

SUPPLEMENTARY INFORMATION: FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j) and 5 CFR 1320.13). This information is needed immediately so that the agency can decide whether an applicant is a “small business” within the meaning of MDUFMA. A small business is eligible for a reduced or waived fee for a medical device application or submission that is subject to a user fee under MDUFMA. If an applicant is not a small business, it must pay the standard (full) fee for any medical device application or submission it submits to FDA. FDA is requesting this emergency processing to implement 21 CFR 738(d)(2)(B) and (e)(2)(B) (§ 738(d)(2)(B) and (e)(2)(B)) of the Federal Food, Drug, and Cosmetic Act (the act); these provisions were added to the act by section 102 of MDUFMA. The use of normal clearance procedures would likely result in the prevention or disruption of this collection of information, thereby subjecting applicants who would otherwise qualify as a small business to the statutory requirement to pay a standard (full) fee rather than a reduced fee.

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.

FY 2003 MDUFMA Small Business Qualification Certification (Form FDA 3602)

MDUFMA (Public Law 107–250) 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. 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.

Under MDUFMA, 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.

Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice announcing the availability of the guidance entitled “FY 2003 MDUFMA Small Business Qualification Worksheet and Certification.” The guidance describes the criteria FDA will use to decide whether an entity qualifies as a MDUFMA

small business and helps prospective applicants understand what they need to do to meet the criteria for FY 2003.

Respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this information collection as follows:

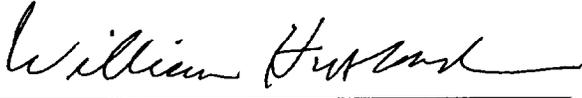
TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA Form Number	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3602	100	1	100	1	100

¹ 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 application, a premarket report, a panel track supplement, efficacy supplement, 180-day supplement, or a real time supplement to FDA during FY 2003.

Dated: 3-10-03
March 10, 2003.



William K. Hubbard,
Associate Commissioner for Policy and Planning.

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