J. Where To Obtain Additional Information

This, and other CDC announcements, the necessary applications, and associated forms can be found on the CDC Web site, Internet address: *http://www.cdc.gov*. Click on ''Funding'' then ''Grants and Cooperative Agreements''.

For general questions about this announcement, contact: Technical Information Management, CDC Procurement and Grants Office, 2920 Brandywine Rd., Atlanta, GA 30341–2700, Telephone: 770–488–2700.

For business management and budget assistance, contact: Ann Gatwood, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341–4146, Telephone: 770–488–2895, E-mail address: *glg4@cdc.gov*.

For program technical assistance, contact: Jinan Saaddine, Division of Diabetes Translation, CDC National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, NE., Mailstop K–10, Atlanta, GA 30341, E-mail: *JSaaddine@cdc.gov*, Telephone: (770) 488–1274.

Dated: July 14, 2003.

Sandra R. Manning,

CGFM, Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 03–18235 Filed 7–17–03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Docket No. 2003N–0311

Agency Information Collection Activities; Proposed Collection; 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 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. 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. In the **Federal Register** of March 26, 2003 (68 FR 14664), FDA published a notice announcing OMB's approval of this collection of information (OMB control number 0910–0508). Since this was an emergency approval that expires on October 31, 2003, FDA is following the normal PRA clearance procedures by issuing this notice.

DATES: Submit written or electronic comments on the collection of information September 16, 2003.

ADDRESSES: Submit electronic comments on the collection of information via the Internet at: *http://www.fda.gov/dockets/edockethome*. Submit written comments on the collection of information to the Divsion 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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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, including each proposed extension of an existing 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: (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.

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

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

TABLE 1. — ESTIMATED ANNUAL REPORTING BURDEN[1]

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

[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 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: July 11, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03–18160 Filed 7–17–03; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (301) 443–7978.

2004 National Survey on Drug Use and Health—(OMB No. 0930–0110, Revision)—The National Survey on Drug Use and Health (NSDUH), formerly the National Household Survey on Drug Abuse (NHSDA), is a survey of the civilian, noninstitutionalized population of the United States 12 years old and older. The data are used to determine the prevalence of use of tobacco products, alcohol, illicit substances, and illicit use of prescription drugs. The results are used by SAMHSA, ONDCP, Federal government agencies, and other organizations and researchers to establish policy, direct program activities, and better allocate resources.

As with all NSDUH/NHSDA surveys conducted since 1999, the sample size of the survey for 2004 will be sufficient to permit prevalence estimates for each of the fifty states and the District of Columbia. For the 2004 survey, additional questions in the following substantive areas are planned: adult mental health treatment (three additional questions to obtain more detail on unmet mental health treatment need, and on alternative mental health treatment received); drug treatment (four questions on age at first treatment for alcohol and/or drug use); prior substance use (expanded 2003's prior marijuana and cigarette use module to collect information on age at last use for each core substance respondent reported last using over 30 days); depression (separate modules for adolescents and adults based on adaptations of existing modules used in the National Comorbidity Survey). The following questions are planned to be deleted from the 2004 survey: speciality cigarettes (questions about clove and bidi use); amount paid for cigarettes in the past 30 days; and youth access to cigarettes. Three to four years of data have been collected on these questions, which may be included again in future surveys as the need arises. The total annual burden estimate is shown below:

	Number of respondents	Responses per respondent	Average burden per response (hr.)	Total burden (hrs)
Household Screening	182,250	1	0.083	15,127
Interview	67,500	1	1.0	67,500
Screening Verification	5,559	1	0.067	372
Interview Verification	10,125	1	0.067	678
Total	182,250	.....	.....	83,677