scheduled for the meeting; or you may contact the Board's Web site at *http://www.federalreserve.gov* for an electronic announcement that not only lists applications, but also indicates procedural and other information about the meeting.

Board of Governors of the Federal Reserve System, August 25, 2006.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 06–7253 Filed 8–25–06; 1:17 pm]

BILLING CODE 6210–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0203]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; User Fee Cover Sheet; Form FDA 3397

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 review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 28, 2006.

ADDRESSES: 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: FDA Desk Officer, FAX: 202–395–6974.

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

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.

User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under sections 735 and 736 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g and 379h), the Prescription Drug User Fee Act of 1992 (PDUFA) (Public Law 102–571), as amended by the Food and Drug Administration Modernization Act of 1997 (Public Law 105–115), and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, which includes the Prescription Drug User Fee Amendments of 2002 (Public Law 107–188), FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements. Under this authority, pharmaceutical companies pay a fee for certain new human drug applications, biologics license applications, or supplements submitted to FDA for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. Form FDA 3397, the user fee cover sheet, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application with the actual application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of new drug applications, biologics license applications, and supplemental applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2005, there are an estimated 243 manufacturers of products subject to PDUFA. However, not all manufacturers will have any submissions, and some may have multiple submissions in a given year. The total number of annual responses is based on the number of submissions received by FDA in FY 2005. CDER estimates 3,085 annual responses that include the following submissions: 101 new drug applications; 3 biologics license applications; 1,915 manufacturing supplements; 921 labeling supplements; and 145 efficacy supplements. CBER estimates 676 annual responses that include the following submissions: 6 biologics license applications, 614 manufacturing supplements, 46 labeling supplements, and 10 efficacy supplements. Based on previous estimates, the rate of submissions is not expected to change significantly in the next few years. The estimated hours per response are based on past FDA experience with the various submissions, and range from 5 to 30 minutes. The hours per response are based on the average of these estimates.

In the **Federal Register** of May 25, 2006 (71 FR 30144), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Form	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
FDA 3397	243	15.48	3,761	0.30	1,128

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

Dated: August 22, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–14266 Filed 8–28–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0327]

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. This notice solicits comments on the proposed collection of information that 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).

DATES: Submit written or electronic comments on the collection of information by October 30, 2006.

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: Denver Presley, Jr., Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

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 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, 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. FDA published a **Federal Register** notice on August 2, 2006 (71 FR 43784), announcing fees for fiscal year (FY) 2007. 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.

For FY 2006, you can qualify for a small business fee discount under MDUFMA if you reported gross receipts or sales of no more than $100 million on your Federal income tax return for the most recent tax year. If you have any affiliates, partners, or parent firms, you must add their gross receipts or sales to yours and the total must be no more than $100 million. If your gross receipts or sales are no more than $30 million (including all of your affiliates, partners, and parent firms), you will also qualify for a waiver of the fee for your first (ever) premarket application (PMA, product development protocol (PDP), biologics licensing application (BLA), or Premarket Report). 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 is available in guidance document, ''Guidance for Industry and FDA: FY 2006 MDUFMA Small Business Qualification Worksheet and Certification.'' This guidance describes 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 2006 and subsequent fiscal years.

Description of Respondents: Respondents will be businesses or other for-profit organizations.

FDA estimates the burden of this collection of information 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	2,000	1	2,000	1	2,000
Total Hours					2,000

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